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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92052897
Party	Plaintiff Thomas Sköld
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Submission	Motion for Summary Judgment
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Signature	/Arthur E Jackson/
Date	05/17/2012
Attachments	PetitionersBriefPublic.pdf ( 16 pages )(422489 bytes ) DeclarationArthurEJackson.pdf ( 3 pages )(333222 bytes ) ExhibitsToAEJDeclarationPUBLIC.pdf ( 100 pages )(4929316 bytes )

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld,	)
Petitioner,	)
	)
V.	)
	) Cancellation No. 92052897
Galderma Laboratories, Inc.,	)
Registrant	)
	)

In the Matter of Registration Nos. 2985751; and 3394514

# BRIEF IN OPPOSITION TO REGISTRANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Petitioner files herewith a Brief in Opposition to Registrant's Motion for Partial Summary Judgment, filed April 27, 2012, and served by mail.

Registrant's Motion and the Facts There Asserted Do Not Establish Registrant's Use of the Class 5 Registration, No. 2985751

Registrant's papers have well established that Cetaphil Restoraderm Skin Restoring Moisturizer is a good..., well, moisturizer. We have a bit of sponsored research in a minor medical journal that asserts that it can be used for long-term management of atopic dermatitis, a form of eczema.<sup>1</sup> We have a marketing executive that asserts the moisturizer and a Cetaphil Restoraderm Skin Restoring Body Wash "were specifically designed to work together as a daily

<sup>&</sup>lt;sup>1</sup> See, Declaration of Arthur E. Jackson ("Jackson Decl.") at ¶5, Exh. A, showing that the National Eczema Association denotes atopic dermatitis as a form of eczema.

regimen to provide continuous relief for those struggling with atopic dermatitis and/or eczema-prone skin." The evidence provided in Registrant's filing shows that its Restoraderm articles are much the same for moisturizing as other available moisturizers. The evidence does not show use in Class 5 of *Therapeutic Skin Care Preparations and Treatment of Skin Disorders*.

TMEP §1402.03 states that "a skin lotion that is medicated should be classified in Class 5, and the identification should indicate that the product is medicated in order to justify its classification in Class 5 rather than in the more commonly understood and assigned Class 3" (emphasis added). So, if a skin lotion is a drug, it can be classified in Class 5, if merely a skin lotion, it is Class 3. What is medicated is established by the United States Food and Drug Administration ("FDA"). Registration of a non-medicated lotion in Class 5 is even more inappropriate here, where the registration in question is for *Therapeutic Skin Care Preparations and Treatment of Skin Disorders*. If the products are not sold as therapeutic (in Class 5) and as a treatment for skin disorders, the registration is no longer being used.

According to Webster's New World Dictionary, Third College Edition, 1988, the meaning of "lotion" is "a liquid preparation used, as on the skin, for cleansing, soothing, healing, etc." Jackson Decl. at ¶6, Exh. B. Petitioner does not think that this definition, taken non-selectively from the first and only source examined, should be in dispute. The definition even comports with TMEP §1402.03 in acknowledging that some lotions may be medicated. A review of Exhibit A of the Registrant's Kee Declaration establishes that Cetaphil Restoraderm Skin Restoring Moisturizer and Cetaphil Restoraderm Skin Restoring Body Wash are such liquid formulations for cleansing and soothing. They are lotions, more specifically, skin lotions.

As will be clearly elucidated below, the Food, Drug and Cosmetic Act ("FD&C Act") establishes that if an article treats a disease it is a drug (i.e., medicated). If an article is promoted

as treating a disease, it is a new drug. If a new drug, it must be approved by the FDA, or it is illegal. The FDA "estimates that in the United States today perhaps as many as several thousand drug products are marketed illegally without required FDA approval." See, CPG Sec. 440.100, a publication of the FDA. Jackson Decl. ¶7, Exh. C. It may be that Cetaphil Restoraderm moisturizer is marketed illegally. However, in its circumspect labeling and presentations made to consumers, Registrant clearly seeks to avoid making the assertion of treating disease. i.e., of providing a therapeutic. It is its public representations that should determine whether Registrant is using the Class 5 registration.

Petitioner submits that it is the public marketing of the lotion as a drug that justifies its inclusion in Class 5 for *Therapeutic Skin Care Preparations and Treatment of Skin Disorders*. A trademark identifies the goods. If a lotion is not sold as a drug, then classification of *Therapeutic Skin Care Preparations and Treatment of Skin Disorders* in Class 5 mis-identifies the goods. If the lotion is publicly sold as not-a-drug, and privately sold as, wink, wink, a drug, then it is against the public interest for a Lanham Act registration to be used to perpetuate such an illegality. Such public teachings that an article is not-a-drug, accompanied by private teachings that it is a drug, are also deceptive or scandalous in violation of Section 2(a) of the Lanham Act (15 U.S.C § 1052(a)). Petitioner submits that a lotion must be publicly marketed as a drug to merit its registration in Class 5, especially as *Therapeutic Skin Care Preparations and Treatment of Skin Disorders*. If the goods asserted to be sold under the 2985751 registration are not so marketed, the mark in Class 5 is abandoned.

According to FD&C Act §201(g)(1) (21 U.S.C. §321(g)(1)), the term "drug" means, among other things, "(B) articles intended for use in... treatment, or prevention of disease in man or other animals."

According to FD&C Act §201(p) (21 U.S.C. §321(p)), a "new drug" is "*[a]ny drug*... the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof..." The statute goes on to exempt certain drugs on the market in 1938, a provision not relevant to the current case. New drugs must be approved under Section 505 of the FD&C Act (21 U.S.C. §355).

As we will see, the "generally recognized" as safe and effective exception to being a new drug is so narrow as to be effectively nonexistent. Assuming the narrowness of the exception for the moment, then if an article treats a disease, and is "prescribed, recommended, or suggested" as such in its labeling or other marketing, it is a new drug requiring regulatory approval for that use.

In <u>United States v. 50 Boxes More or Less</u>, the Court of Appeals for the First Circuit quotes the Supreme Court on the narrowness of the "generally recognized" exception:

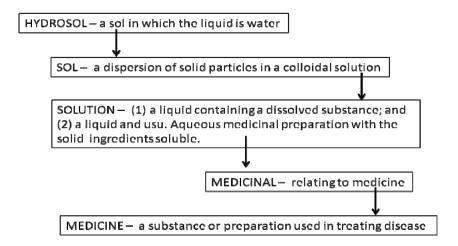
the hurdle of "general recognition" of effectiveness requires at least "substantial evidence" of effectiveness for approval of an NDA [i.e., "new drug" application]. In the absence of any evidence of adequate and well-controlled investigation supporting the efficacy of [a drug], a fortiori, [the drug] ... would be a "new drug" subject to the [new drug] provisions of the Act.

909 F.2d 24, 27-28 (1<sup>st</sup> Cir. 1990), <u>quoting</u>, <u>Weinberger v. Hynson</u>, <u>Westcott & Dunning</u>, <u>Inc.</u>, 412 U.S. 609 (1973). In other words, its not some stray funded publication in a minor journal, or the opinion of a marketing executive, it is only science sufficient to support a new drug application at the Food and Drug Administration that would support that an article is generally

recognized as safe and effective so as to not be a regulated new drug. Nothing in Registrant's filing supports an assertion that these kinds of extensive studies have been conducted.

The Registrant's filing emphasizes the marketing of skin barrier restoration and hydration properties. This is a fancy way to say the article is a moisturizer. In other words, it is a skin lotion. The evidence provided with Registrant's filing shows that the article works about the same as other moisturizers. Fancy words do not transform the skin lotion to a medicine. Promoting, to the public, a skin lotion as a therapeutic makes it a medicine. Promoting in this way without a regulatory approval makes the skin lotion an illegal medicine. Fortunately, for preserving legality, Registrant's public marketing pronouncements do not sell a medicine. Unfortunately, for Registrant, the total lack of any indication of selling or distributing as a medicine indicates abandonment.

The Registrant's filing argues on dictionary definitions. At one time, panels of the Court of Appeals for the Federal Circuit would use "objective" dictionary meanings to construe terms broadly or narrowly, without sufficient regard to context. This practice was strongly proscribed in <a href="Phillips v. AWH Corporation">Phillips v. AWH Corporation</a>, 415 F.3d 1303 (Fed. Cir. 2005)(en banc). In the narrowing direction, under the old practice, one case yielded the ludicrously convoluted reasoning summarized to a bar association group as follows:



Jackson Decl. ¶8, Exh. D. Smart jurists were in this case led astray by the game of dictionary. One can play this game until a dog is a cat, or a plain skin lotion is a medicine. The game of dictionary is a meaningless exercise without a strong tie to context, and a very cautious and skeptical review.

While <u>Phillips</u> is a patent case, its lessons on the limitations of parsing dictionaries are universal. As stated in <u>Phillips</u>:

Dictionaries, by their nature, provide an expansive array of definitions. General dictionaries, in particular, strive to collect all uses of particular words, from the common to the obscure. By design, general dictionaries collect the definitions of a term as used not only in a particular art field, but in many different settings.

<u>Phillips</u> at 1321. As such, "[i]ndiscriminate reliance on definitions found in dictionaries can often produce absurd results. . . . One need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended..." <u>See, Phillips</u> at 1322, <u>quoting Liebscher v. Boothroyd</u>, 258 F.2d 948, 951 (CCPA 1958). Use of a dictionary needs careful consideration of the context.

In the guiding context that is relevant here, TMEP §1402.03 makes clear that a "therapeutic" lotion in Class 5 is medicated, i.e., it is a drug. Registrant's Class 3 (for *Non-Medicated Skin Care Preparations*) registration is what covers its lotion product. Registrant's Class 5 registration was abandoned years ago when Registrant stopped trying to make a medicated (i.e., therapeutic) product.

Two can play the game of dictionary. According to Webster's New World Dictionary, the lead meaning of "therapeutic" is "serving to cure or heal." Another meaning is "of therapeutics." "Therapeutics," in turn, is "the branch of medicine that deals with the treatment and cure of diseases." Jackson Decl. ¶6, Exh. B. So, under this execution of the game of dictionary, you use a "basic and widely available dictionary" and get the right meaning: a drug. It is a meaning that is arrived at without needing an "in-depth knowledge of the relevant field," medicine. The further guiding context of Class 5, a context of Class 5 that speaks to "pharmaceutical preparations," should lead one to discard softer meanings of "therapeutic." In the relevant context, "therapeutic" does not refer to a spa treatment. The guiding context of the United States Patent & Trademark's established practices memorialized at TMEP §1402.03, further helps refine the relevant meaning, i.e., a drug.

Additional guiding context is provided by the Eczema Quick Fact Sheet from the National Eczema Association, as found at Exhibit A of the Jackson Decl. Under the heading "Management of Eczema," the National Eczema Association makes clear that there is a difference between eczema management with a moisturizer, and treatment with a drug. Petitioner submits that recitation by the Association reflects the meaning of "treatment" (and therapeutic) that is understood by the consumer of an eczema management tool.

Consider the Registrant's cagey recitations and links at cetaphilrestoraderm.com: "it helps as part of a dermatologist-recommended daily skin care routine for the management of eczema."

See Exhibit 13 to Amended Petition to Cancel. Exhibit 13, which is a somewhat older version of

<sup>&</sup>lt;sup>2</sup> The only other definitional element of Class 5 in which the Restoraderm products could fall is "sanitary preparations for medical purposes." But if sanitary preparations, the goods would not be *Therapeutic Skin Care Preparations and Treatment Of Skin Disorders*.

Registrant's webpage for Cetaphil Restoraderm, references the National Eczema Association's Seal of Acceptance for "products created or intended for use by personas with Eczema or severe sensitive skin conditions." Even this third party quote does not say that Cetaphil Restoraderm treats eczema. On a side panel of the current website (where a tab has to be clicked to reveal the panel), the website comes the closest to saying treating by saying its "Moisturizer and Body Wash work together to form a gentle daily skin care routine that helps soothe itch, and reduce the redness, dryness and irritation of eczema-prone skin." Jackson Decl. ¶9, Exh. E. But note, this text basically says that the article moisturizes skin that happens to have eczema. The website does not say that the moisturizer (or the Cetaphil Restoraderm body wash) treats eczema.

A careful reading of cited Exhibits A and B to Registrant's Kee Declaration finds no public promotional material that supports a recitation to consumers that the "products were specifically designed to work together as a daily regimen to provide continuous relief for those struggling with atopic dermatitis and/or eczema-prone skin." Thus, this statement in ¶8 of the Kee Declaration is a private opinion, not a part of Registrant's public selling regime. Exhibit B of the Kee Declaration (at p. 7), in fact, shows that a topical steroid *treats* atopic dermatitis, with Cetaphil Restoraderm materials being a useful adjunct to treatment, just as *moisturizers* have long been know to be such adjuncts. If Cetaphil Restoraderm were being promoted to *treat* it would need an approval as a new drug, or its promotion would be illegal.

The allegedly ultra-confidential Exhibits do not provide any evidence that the buying public (as either consumers or dermatologists – those not sitting on Registrant's advisory boards) is presented Cetaphil Restoraderm as a treatment for eczema or atopic dermatitis. There is not a

<sup>&</sup>lt;sup>3</sup> Per the National Eczema Association: "Basic skin care can enhance the effect of prescription drugs, and it can prevent or minimize the severity of eczema relapse." Jackson Decl. ¶10, Exh. F.

hint of an allegation or averment that any effort has been made to obtain a regulatory approval in the United States for selling a *medicated* article that could *therapeutically treat* a disease. Exhibit A to the Jackson Declaration, Eczema Quick Fact Sheet from the National Eczema Association, states that there are only two non-steroidal treatments for eczema, and neither is Cetaphil Restoraderm (they are tacrolimus and pimecrolimus).

The declaration by Cindy Kee mentions "

"But, except ambiguously for four studies described in Exhibit L, we never learn detail on the nature of these studies. They are not asserted to establish that Cetaphil Restoraderm is effective to treat a disease, or that the lotion is "generally recognized, among experts," as set forth in the FD&C Act to be safe and effective in such treatment. Moreover, these studies were not even on Cetaphil Restoraderm, since they were done before there was a formulation for Cetaphil Restoraderm. Kee Declaration at ¶14.

Consider the four of the studies were the basis for the publication on Cetaphil Restoraderm that is Exhibit L to the Kee Declaration.<sup>4</sup> It is safe to assume that the four studies presented in some detail in Exhibit L are Registrant's best evidence that Cetaphil Restoraderm is effective to treat a disease, or that it is "generally recognized, among experts," as set forth in the FD&C Act to be safe and effective in such treatment. It certainly comes up short. It is only studies at least near to as rigorous as those supporting a new drug application that establishes such general recognition. See 50 Boxes, 909 F.2d at 27-28. The paper of Exhibit L is also an assertion of a third party and an employee of Registrant acting as a research scientist, not the

<sup>&</sup>lt;sup>4</sup> It is unclear how to interpret ¶14 of the Kee Declaration, stating that the studies were done before there was a formulation for Cetaphil Restoraderm, in light of ¶19 asserting that four of these studies were the basis for the Exhibit L publication on Cetaphil Restoraderm.

assertion made to the public by Registrant. There is no suggestion in the Registrant's filing that this study or anything else will be the basis for filing a new drug application, in support of which experimental use Class 5 *might* have been appropriate.

Consider the sponsored research of Exhibit L to the Kee Declaration in more detail. The Exhibit L article never says that Cetaphil Restoraderm Moisturizer treats atopic dermatitis. It says that it is suitable for "long-term management" of atopic dermatitis. Exhibit L at pp. 744 (Abstract) and 748 (last paragraph). The reference to "short-term *treatment*" in the last paragraph at p. 748 is clearly a reference to the study on using Cetaphil Restoraderm Moisturizer with a treatment steroid during flares.

The Exhibit L paper makes moisturizing comparisons to other moisturizers, namely Physiogel AI cream (Steifel Laboratories) and Eucerin Calming Cream (Beiersdorf). Neither of these two comparative products has the National Eczema Association's Seal of acceptance. See Jackson Decl., Ex. G. The evidence on hydration (Fig. 1) shows that Cetaphil Restoraderm Moisturizer and Eucerin Calming Cream are virtually identical in this non-rigorous test. Just two of four timepoints are said to yield a modest difference that is asserted to be of statistical significance. When one picks and chooses points of significance, there is no significance. When n=30 in a physiological experiment, and when the observed differences are small, statistical significance needs to be very high, and reproduced in replicated studies, for the result to have hopes of being modestly compelling.<sup>5</sup> A visual inspection of Fig. 1 will assure one's common sense that there is no difference between the top trace (Cetaphil Restoraderm Moisturizer) and

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<sup>&</sup>lt;sup>5</sup> The evidentiary weakness of the recitation of a p-value, especially when the observed differences are small is well known, as attested to by the two scientific abstracts found at Exhibit K to the Jackson Decl.

the trace slightly below it (Eucerin Calming Cream). For the more important study of skin barrier function (Fig. 2), no statistical difference is asserted between the moisturizers. Thus, Registrant's evidence shows that Cetaphil Restoraderm Moisturizer is a moisturizer much like other moisturizers.

Of the statements provably ascribable to Registrant, certain statements of the Kee Declaration come closest to asserting a treatment of a disease. Yet even these non-public statements do not quite get there. These statements are:

8. The RESTORADERM products were specifically designed to work together as a daily regimen to provide continuous relief for those struggling with atopic dermatitis and/or eczemaprone skin. *See* Exhibits A, B.

This statement quite clearly does not assert a treatment for atopic dermatitis or eczema.

10. Registrant's RESTORADERM Skin Restoring Body Wash is a foaming wash specially formulated to help skin retain moisture and maintain the skin barrier function. *See* Exhibits A, B.

This statement quite clearly does not assert a treatment for atopic dermatitis or eczema.

11. Registrant's RESTORADERM Skin Restoring Moisturizer is specially formulated to restore moisture to atopic and/or eczema-prone skin and to help replenish, repair, and protect the skin's natural moisture barrier. *See* Exhibits A. B.

This statement quite clearly does not assert a treatment for atopic dermatitis or eczema.

Paragraph 9 of the Kee Declaration asserts that Cetaphil Restoraderm has marvelous moisturizer ingredients. Yet note that by Registrant's Exhibit L to its Kee Declaration, Cetaphil Restoraderm is not particularly superior to other moisturizers, which presumably lack these ingredients. Most importantly, nothing in ¶9 asserts a treatment for atopic dermatitis or eczema. Nothing in ¶9 tells

us how these ingredients are "clinically proven." Are they clinically proven not to kill the user? Are they clinically proven to reduce wrinkles? Who knows. Paragraph 9 is a red herring.

The closest Registrant's papers come to asserting relevant activity in a time frame that might help it avoid a presumption of abandonment is in its writings at pp. 9 - 11 of its Motion. But this activity relates to a moisturizing lotion.

or can be presumed not to relate to testing the skin lotion as a therapeutic. The recitations about an asserted bona fide intent to use what is framed as a fairly explicitly pharmaceutical Class 5 registration (p. 9 of Registrant's Motion), does not speak to its activity in the period since say May 1, 2009.

Having filed this motion for Summary Judgment, and presented only this evidence, Petitioner submits that Registrant has near to conceded that it has no evidence that it markets Cetaphil Restoraderm as a medicated article. By the same reasoning, Registrant has near to conceded that it has no evidence that it has acted to seek a medicated article in the last three years. Petitioner submits that Registrant has not sought a medicated "Restoraderm" article since 2007. As such, Petitioner submits that Registrant has near to conceded that it has abandoned its Class 5 registration.

A focus of this dispute is whether for moisturizing skin lotions there exists a distinction between Class 3 and Class 5. TMEP §1402.03 suggests that such a distinction does exist. If TMEP §1402.03 is meaningful, the only way to identify a "medicated" lotion that is properly and legally marketed in the United States as such is via the FD&C Act. Registrant appears <u>not</u> to

have found binding authority to the effect that in this context Class 5 is not meaningfully distinct from Class 3 with respect to moisturizing skin lotions.

Assuming for the sake of argument that in some contexts a lotion can be Class 5 and Class 3, still this does not allow a Class 5 registration for *Therapeutic Skin Care Preparations* and *Treatment Of Skin Disorders* where there is no marketing of a therapeutic or a treatment. Such an overlapping Class 5 registration might for example be for goods analogous to "sanitary preparations for medical purposes," where an overlapping Class 3 registration might be for, as here, *Non-Medicated Skin Care Preparations*. But Registrant, when it intended to sell a therapeutic, and to distribute to appropriate clinical trials, opted to register for *Therapeutic Skin Care Preparations and Treatment Of Skin Disorders*. Having abandoned selling therapeutic lotions, it abandoned this registration.

Petitioner submits that Registrant's motion should be denied, as Petitioner's filing has not established that Registrant is using the Class 5 registration.

#### Needed Discovery Relating to Registrant's Motion

If the Board does not accept Petitioner's contention that Registrant has not supported an assertion of use of the Class 5 registration, then whether Registrant has abandoned selling therapeutic lotions is still in factual dispute, as evidenced by Exhibits H, I and J of the Declaration of Arthur Jackson.

Exhibit H is a copy of Registrant's asserted response to Petitioner Sköld's First Set Of Interrogatories and Requests For Production. Registrant was non-responsive to each and every one of these requests, even those that clearly relate to the priority contest. Interrogatories 10 through 22 seek information about development under the mark Restoraderm of a medicated

material. Interrogatories 24 and 25 seek to identify which products are sold under Reg. No. 2985751, and which are sold under Reg. No. 3394514, thereby seeking to confirm that the same products are asserted to be sold under these registrations, even though the descriptions of goods for the one exclude the goods for the other (*Therapeutic Skin Care Preparations and Treatment Of Skin Disorders* vs. Non-Medicated Skin Care Preparations). This information is needed before the Registrant's Motion could be decided in Registrant's favor. Petitioner expects a more forthright response to these interrogatories after this motion is decided.

Exhibit I is a copy of Registrant's asserted response to Petitioner Sköld's First Request for Admissions. Registrant denied each and every request, even those that are believed to be objectively virtually undeniable. (See for example Request for Admission No. 27.)

Exhibit J is a copy of Petitioner Sköld's Second Set Of Interrogatories and Requests For Production, which in Interrogatories 42 – 46 seeks facts surrounding some of Registrant's denials set forth in Exhibit I, and related to development under the mark Restoraderm of a medicated material. This information is needed before the Registrant's Motion could be decided in Registrant's favor.

Petitioner respectfully submits that Registrant's motion should be denied, as there are still material facts in contention.

#### Conclusion

In light of the foregoing, Petitioner submits that the Motion should be denied.

Respectfully submitted,

Date: May 17, 2012

Arthur E. Jackson, Esq. New Jersey Bar No. 00288-1995

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld,	)
Petitioner,	)
	)
V.	)
	) Cancellation No. 92052897
Galderma Laboratories, Inc.,	)
Registrant	)
	)

#### **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Petitioner's Brief in Opposition to Motion for Partial Summary Judgment (PUBLIC version) was sent by email on this 17<sup>th</sup> of May, 2012 to:

Jeff.Becker@haynesboone.com

I hereby certify that a copy of the foregoing Petitioner's Brief in Opposition to Motion for Partial Summary Judgment (TRADE SECRET/COMMERCIALLY SENSITIVE version) was sent first class mail, postage pre-paid on this 17<sup>th</sup> of May, 2012 to:

Attn: JEFFREY M. BECKER HAYES AND BOONE, LLP 2323 VICTORY AVENUE, SUITE 700 DALLAS, TX 75219 UNITED STATES

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Sköld,	)
Petitioner,	)
	)
V.	)
	) Cancellation No. 92052897
Galderma Laboratories, Inc.,	)
Registrant	)
	)

#### **DECLARATION OF ARTHUR E. JACKSON**

I, Arthur E. Jackson, declare as follows:

- 1. I am Counsel at the law firm of Moser Taboada and counsel for Petitioner Thomas Sköld in this Cancellation.
- 2. I am over the age of eighteen (18) and am competent to make this declaration.
- 3. I have personal knowledge of the matters which are the subject of this declaration.
- 4. This declaration is made to authenticate certain documents in support of Petitioner's response to Registrant's Motion for Partial Summary Judgment and confirm certain facts in connection with this Cancellation.
- 5. Exhibit A is a true and correct copy of a screen shot of the website http://www.nationaleczema.org/living-with-eczema/eczema-quick-fact-sheet as accessed 11 May 2012.
- 6. Exhibit B is true and correct copy of pp. 800, 1387 of Webster's New World Dictionary, Third College Edition, Simon a& Shuster, Inc., 1988. The definition of "lotion" found at p. 800 has only one listed meaning, and the definition is the first and only definition examined in connection with the drafting of the concurrently filed Brief in Opposition to Registrant's Motion for Partial Summary Judgment. This "lotion" definition was consulted by the undersigned without guidance or advice from any other person.
- 7. Exhibit C is a true and correct copy of CPG Sec. 440.100, Marketed New Drugs Without Approved NDAs and ANDAs =, as downloaded 11 May 2012 from http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074 382.htm.

- 8. Exhibit D is a true and correct copy of a six slides published in the program of the Twenty-First Annual Joint Patent Practice Seminar, April 21, 2005, in connection with a presentation by S. Peter Ludwig.
- 9. Exhibit E is a true and correct copy of a screen shot of the website http://www.cetaphil.com/products/restoraderm-moisturizer, as accessed 8 May 2012, with the "SPECIAL INSTRUCTIONS" tab activated.
- 10. Exhibit F is a true and correct copy of a screen shot of the website http://www.nationaleczema.org/living-with-eczema/bathing-moisturizing as accessed 11 May 2012.
- 11. Exhibit G is a true and correct copy of a screen shot of the website http://www.nationaleczema.org/seal-acceptance/product-directory-personal-care as accessed 11 May 2012.
- 12. Exhibit H is a true and correct copy of Registrant's Response to Petitioner Sköld's First Set of Interrogatories and Requests for Production of Documents and Things.
- 13. Exhibit I is a true and correct copy of Registrant's Response to Petitioner Sköld's First Request for Admissions.
- 14. Exhibit J is a true and correct copy of Petitioner Sköld's Second Set of Interrogatories and Requests for Production of Documents and Things.
- 15. Exhibits 8, 9, 12 and 13 of the Petitioner's Amended Petition are true and correct copies of the items identified in the Amended Petition.

I declare, under penalty of perjury under the laws of the United States of America and 28 U.S.C. § 1746, that the foregoing is true and correct, and that this declaration was executed this 17 day of May 2012 in Shrewsbury, New Jersey.

Respectfully submitted,

Date: 17 May 2012

By: Arthur E. Jackson, Esq.

New Jersey Bar No. 00288-1995

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**MOSER TABOADA** 

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Attorney for Petitioner

# PUBLIC IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld,	)
Petitioner,	)
v.	)
Galderma Laboratories, Inc., Registrant	) Cancellation No. 92052897 )
	)

#### **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Declaration of Arthur E. Jackson was sent by email on this  $17^{th}$  of May, 2012 to:

Jeff.Becker@haynesboone.com



## Exhibit A – Jackson Declaration

(Screen Shot Of The Website http://www.nationaleczema.org/living-with-eczema/eczema-quick-fact-sheet)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514





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#### ECZEMA QUICK FACT SHEET

#### WHAT IS ECZEMA?

Eczema is a general term for any type of dermatitis or "itchy rash". There are several skin diseases that are eczemas; a partial list of eczemas includes:

- · atopic dermatitis
- · contact dermatitis
- dyshidrotic eczema
- nummular eczema
- · seborrheic dermatitis

All types of eczemas cause itching and redness and some will blister, weep or peel.

#### **ATOPIC DERMATITIS (AD)**

Atopic dermatitis is the most severe and chronic (long-lasting) kind of eczema. Atopic dermatitis is a disease that causes itchy, inflamed skin. It almost always begins in childhood, usually during infancy. Physicians estimate that 65 percent of eczema patients are diagnosed in the first year of life and 90 percent of patients experience it before age five. Often the symptoms fade during childhood, though "most" will have AD for life. It is estimated that atopic dermatitis affects over 30 million Americans. It typically affects the insides of the

during childhood, though "most" will have AD for life. It is estimated that atopic dermatitis affects over 30 million Americans. It typically affects the insides of the elbows, backs of the knees, and the face but can cover most of the body. Atopic dermatitis falls into a category of diseases called atopy, a term originally used to describe the allergic conditions asthma and hay fever. Atopic dermatitis was included in the atopy category because it often affects people who either suffer from asthma and/or hay fever or have family members who do; but now have been genetically connected. Physicians often refer to these three diseases as the "atopy triad". The disease by its very nature can be episodic. People with atopic dermatitis tend to have high staph levels on their skin, although atopic dermatitis is not infectious to other people.



Contact dermatitis is a reaction that can occur when the skin comes in contact with certain substances, which can cause skin inflammation. Irritants are substances that cause burning, itching or redness. Common irritants include solvents, industrial chemicals, detergents, fumes, tobacco smoke, paints, bleach, woolen fabrics, acidic foods, astringents and other alcohol (excluding cetyl alcohol) containing skin care products, and some soaps and fragrances. Allergens are usually animal or vegetable proteins from foods, pollens, or pets. Contact dermatitis is most often seen around the hands or parts of the body that touched the irritant/allergen.

#### **DYSHIDROTIC DERMATITIS (POMPHOLYX)**

This is a blistering type of eczema, which is twice as common in women. It is limited to the fingers, palms and soles of the feet. Your hands may have itchy, scaly patches of skin that flake constantly or become red cracked and painful.

#### **NUMMULAR DERMATITIS (DISCOID)**

Dry skin in the winter months can cause dry non-itchy round patches. It can affect any part of the body particularly the lower leg. One or many patches appear, and may persist for weeks or months. Discoid eczema does not run in families, and unlike atopic dermatitis, it is not associated with asthma. It does not result from food allergy. It is not infectious to other people, although bacteria sometimes secondarily infect it. Discoid eczema is more common in males.

#### SEBORRHEIC DERMATITIS

Red, scaly, itchy rash in various locations on the body. The scalp, sides of the nose, eyebrows, eyelids, and the skin behind the ears and middle of the chest are the most common areas affected. Dandruff (as seborrheic, is caused by a fungal infection) appears as scaling on the scalp without redness. Seborrhea is oiliness of the skin, especially of the scalp and face, without redness or scaling. Seborrheic Dermatitis has both redness and scaling.

#### **MANAGEMENT OF ECZEMA**

#### Do I want to use prescription drugs or over the counter medications?

Over-the-counter (OTC) medications are available without a prescription because they contain the lowest potency of active ingredients. They are not designed to treat the causes of a disease, but to give some relief of symptoms. Many good moisturizers are available as OTC products. They are important in terms of prevention and maintenance to reduce eczema's impact. Regular use of these products may reduce the frequency of flare-ups. Prescription medicines, by contrast, are usually much more powerful in providing some relief of the symptoms. They are closely regulated in the U.S. by the Food and Drug Administration (FDA), and are approved for use in treating a specific disease only after they have demonstrated effectiveness and safety. No prescription drug is free of side effects, and FDA approval is given to drugs with the understanding that they must be used with caution to avoid the negative effects which could result in something worse than the disease itself. Consequently, these drugs must be administered under the watchful eye of a licensed prescriber-a doctor, or in some states, a nurse practitioner.

#### WHAT ARE FDA APPROVED PRESCRIPTION THERAPIES?

Topical steroids have been the standard treatment for eczema, with oral steroids being prescribed only for severe flare-ups. Recently, however, the FDA has approved a new class of drugs called Topical Immunomodulators (TIMs). At this time there are two FDA approved non-steroid drugs: tacrolimus and

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Cider Vinegar Warm Bath

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pimecrolimus. Topical anesthetics, antibiotics, antibioti

#### WHAT ABOUT ALTERNATIVE OR COMPLIMENTARY MEDICATION?

Alternative medications also have ingredients that may have irritating or allergenic effects for some people, as with any treatments. It is important to discuss with your physician any alternative medication that you may purchase at a health food store as it may have an adverse reaction to your eczema or another medication you may be taking.

#### ARE THERE PLANTS AND VEGETABLES TO AVOID?

Everyone knows about obvious culprits like poison ivy, poison oak and stinging nettles, but for people with eczema trying to avoid any plants with fuzzy leaves and stems is a good idea. Alliums, which include garlic, onions, chives, and leeks, tend to contain allergens that are more irritant than allergen. Citric fruits like lemons, limes and oranges may cause phototoxicity problems. You can get a severe rash from contact with a mango rind. The saps of certain trees are also phototoxic. Daisies (member of a family which includes dandelions, artichokes, chrysanthemum, sunflowers and yarrow) contain a variety of the allergens called sesquiterpene lactones in their stems, leaves, and flowers. If handled, they can produce a localized rash, and they (particularly dried ragweed) may also cause airborne contact dermatitis. Tulips contain an allergen called tuliposideA that often causes a fissured, fingertip dermatitis called "tulip fingers". Poinsettias are also very irritating mostly because of a sticky sap it exudes. Handle all plants diligently (or with latex free gloves).

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## Exhibit B – Jackson Declaration

(pp. 800, 1387 of Webster's New World Dictionary, Third College Edition)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514 lotic / Louvain

lotic (lot'ik) adj. [< L lotus, a washing (< lautus, pp. of lauere, to wash: see LAVE!) + -10] Ecol. designating, of, or living in flowing water, as rivers: cf. LENTIC

lo tion (lo'shan) n. [ME loscion < L lotio (gen. lotionis) < lotus: see prec. ] a liquid preparation used, as on the skin, for cleansing, sooth-

ing, healing, etc Lotta (lät'a) a feminine name: see CHARLOTTE

Lotta (lat. a) a tentime name.

lotte (lat) n. Fr. name for MONKFISH

lotterly (lat'er a) n., pl. -teries MFr loterie < MDu loterije < lot,

Lot 1 a game of chance in which people buy numbered tickets, and
prizes are given to those whose numbers are drawn by lot: sometimes

sponsored by a state or organization as a means of raising funds 2 rany undertaking that involves chance selections, as by the drawing

of lots [military draft lottery]

of lots [military draft lottery]

Lottie or Lotty (lät'e) a feminine name: see CHARLOTTE

lotto (lät'o) n. It < Fr lot < MDu: see Lot I a game resembling bingo

lotus (lōt'es) n. IL < Gr lottos < Heb lot I fr. Legend a) a fruit

that was supposed to induce a dreamy

languor and forgetfulness b) the plant

legend this fruit variously supposed to

languor and forgetfulness b) the plant bearing this fruit, variously supposed to be the date, the jujube, etc. 2 any of various waterlilies, esp. the white lotus (Nymphaea lotus), once sacred in Egypt, or the pink or white Asian lotus (Nelumbo nucifera), used as a religious symbol in Hinduism and Buddhism 3:a representation of any of these plants in representation of any of these plants in aucient, esp. Egyptian, sculpture and architecture 4 any of a genus (Lotus) of



architecture 4 any of a genus (Lotus) of plants of the pea family, with irregular, pinnate leaves and yellow, purple, or white flowers Also sp. lotos lojtus-eatler (-et'ar) n. in the Odyssey, one of a people who ate the fruit of the lotus and consequently became indolent, dreamy, and forgretful of duty.

forgetful of duty
forgetful of duty
lotus land 1 the land of the lotus-eaters, or any fabulous, dreamlike
setting 2 [Slang] Hollywood and its film industry; thought of as
glittery and alluring, not like the real world: also Lo'tus-land'
lotus position in yoga, an erect sitting posture with the legs crossed
and with each foot, sole upturned, resting on the upper thigh of the

opposite leg opposite leg louche (louche (louc

louche (loosh) adj. [Fr, lit., squinting < L lusca, fem. of luscus, one-eyed ] questionable; shady; odd loud (loud) adj. [ME < OE hlud, akin to Ger laut < IE base \*kleu-, to hear, listen > L cluere, to be spoken of, esteemed.] 1 striking with force on the organs of hearing; strongly audible: said of sound 2 making a sound or sounds of great intensity [a loud bell] 3 noisy 4 clamorous; emphatic; insistent [loud denials] 5 [Colloq.] too'vivid; flashy 6 [Colloq.] unrefined; vulgar 7. [Dial.] strong or offensive, as in smell —adv. in a loud manner —loud'ish adj. —loud'ly adv.—loud'ness n. loud'ness n. louden (loud'n) vt., vt. to make or become loud or louder loud hailer (loud' hāl'ar) n. BULLHORN

loud-mouthed (-mouthd', -moutht') adj. talking in a loud, irritating -loud'mouth' n.

voice—toug mouth n. loud-speakler (-spek'er) n. a device for converting electrical signals to sound waves which are radiated into the air Lou Geh-rig's disease (loo ger'igz) [after (Henry) Lou(is) Gehrig (1903-41), U.S. baseball player who died of the disease AMYOTROPHIC LATERAL SCLEROSIS

lough (läkh) n. [ME, prob. < Gael & OEr loch, LOCH] 1 a lake 2 an

Inough (lakh) n. [ME, prob. < Gael & OEr loch, LOCH] 1 a lake 2 an arm of the sea louis (150'e) n., pl. lou'is (-ēz) Louis D'or Louis (150'e) n., pl. lou'is (-ēz) Louis (-ēx) n. louis

Loulis (lov'is), Joe (born Joseph Louis Barrow) 1914-81; U.S. boxer:

Louis (loō'is), Joe (horn Joseph Louis Barrow) 1914-81; U.S. boxer: world heavyweight champion (1937-49)

Loui-sa (loo ē'zə) [It] a feminine name: see Louise
louis d'or (loō'e dor') [Fr, lit., gold louis: orig. after Louis XIII] 1

an old French gold coin of varying value, issued through the reigns of Louis XIII-Louis XVI 2 a later French gold coin worth 20 francs
Louise (loo ēz') [Fr, fem. of Louis] 1 a feminine name: dim. Lou,
Lulu; var. Eloise; equiv. It. Louisa

Louise, Lake [after Princess Louise Alberta, daughter of Queen
Victoria & wife of the Marquess of Lorne, Cdn gov. gen. (1878-83) ]

small lake in SW Alberta, Canada, in Banff National Park
Loui-si-anja (loo ē'zē an'a, loo'a zē-) [Fr La Louisianne, name for the

Mississippi valley, after Louis XIV. Southern State of the U.S. on the Gulf of Mexico: admitted, 1812; 48,523 sq. mi. (126,160 sq. lm); pop. 4,204,000; cap. Baton Rouge: abbrev. LA or La—Louisian or Louisian adj., n.
Louisiana Purchase land bought by the U.S. from France in 1803

for \$15,000,000: it extended CANADA

from the Mississippi to the Rocky Mountains & from the Gulf of Mexico to Can-

Napoleon (born Louis Charles Louis Napoleon
Bonaparte) 1808-73; president of France (1848-52) & as Napoleon III, emperor (1852-71): deposed: nephew

of Napoleon I
Louis Philippe (fi lēp')
1773-1850; king of France
(1830-48): abdicated in

(1830-48): addicated in Louisiana Purchase Revolution of 1848

Louis Qua-torze (ka tôrz') designating or of the style of furniture, architecture, etc. of the time of Louis XIV of France, characterized by massive, baroque forms and lavish ornamentation

and lavish ornamentation

Louis Quinze (kanz) designating or of the style of furniture, architecture, etc. of the time of Louis XV of France, characterized by rococo treatment with emphasis on curved lines and highly decorative forms based on shells, flowers, etc.

Louis Seize (sez) designating or of the style of furniture, architecture, etc. of time of Louis XVI of France, characterized by a return to straight lines symmetry, and classic ornamental details

ture, etc. of time of Louis XVI of France, characterized by a return to straight lines, symmetry, and classic ornamental details

Louis Treize (trez) designating or of the style of furniture, architecture, etc. of the time of Louis XIII of France, characterized by Renaissance forms, rich inlays, etc.

Louis-ville (105'e vil; locally 105'o val) [after Louis XVI] city in N Ky., on the Ohio River: pop. 298,000 (met. area 906,000)

Rounge (louni) vi. lounged, loung'ing [15th-c. Scot dial. < ? lungis, laggard, lout < OFr longis < L Longinus, apocryphal name of soldier who lanced Jesus in the side: sense infl. in OFr by assoc with longe, long, slow < L longus, Long'] 1 to stand, move, sit, lie, etc. in a relaxed or lazy way; loll 2 to spend time in idleness—vt. to spend by lounging (to lounge the summer away)—n. 1 an act or time of lounging 2 [Archaic] a lounging gait or stroll 3 a) a room, as in a hotel or theater, equipped with comfortable furniture for lounging hotel or theater, equipped with comfortable furniture for lounging b) COCKTAIL LOUNGE 4 a couch or sofa, esp. a backless one with a headrest at one end —loung/er n.

headrest at one end —loung'er n.

\*lounge car a railroad car where passengers may lounge in comfortable chairs and obtain refreshments

\*lounge lizard [Slang] an indolent, pleasure-seeking man who frequents lounges, nightclubs, etc. where rich people or socialities gather loup (loup, lop, loöp) vi., vt. [ME, akin to leap, hleap: see LEAP]

[Scot.] to leap —n. [Scot.] a leap

loup (loo) n. [Fr] a European sea bass Also called loup de mer (lood mer')

tion (loop) n. [Fr < MFr, gem of imperfect transparency, shapeless iron lump, prob. < or akin to OHG luppa, lumpy mass: see LOB a small, high-powered magnifying lens held or worn close to the eye.

loup-ga|rou (loo ga roo') n., pl. loups-ga|rous (loo ga roo') | Fr < loup, wolf (< L lupus) + garou, werewolf < OFr garolf < Frank \*werwulf, akin to OE werwulf, werewolf | werewolf

lour (lour) vi., n. LOWER<sup>2</sup>
Lourenico Marques (lo ren'so mär'kes; Port lô ren'soo mär'kezh)

old name of MAPUTO

louse (lous; also, for v., louz) n., pl. lice [ME lous < OE lus (pl. lys), akin to Ger laus < IE \*lus > Welsh. lleuen; Bret laouen [1 a] any of an order (Anoplura) of small, flat, wingless insects with sucking mouthparts, parasitic on the skin or hair of humans and some other mammals; esp., the human body louse (Pediculus humanus corporis) and head louse (P. h. capitis) b) any of various arthropods that suck blood or juice from other animals or plants 2 bid louses 3 any of various other small insects, arachnids, and crustaceans that are not parasitic, as the book louse or wood louse 4 pl. lous'es [Slang] a person regarded as mean, contemptible, etc.—vt loused, lous'ing [Rare] to delouse —\*louse up [Slang] to botch spoil; ruin

spoil; ruin louse-wort (-wert') n. [so called because sheep feeding on the plant were said to become infested with vermin ] any of a genus (Pedicu laris) of perennial plants of the figwort family, with pinnate divided leaves and spiked clusters of yellow, rose, or purple flower lously (lou'zē) adj. lous[ier] lous[ier] t infested with lice 2 covers with specks: said of silk 3 [Slang] dirty, disgusting or contemptible 4 [Slang] poor; inferior: a generalized epithet of disapproval & well supplied or oversupplied (with) —lous[ier] adv. —lous[ies] n.

lout¹ (lout) n. [prob. < or akin to Me lutien, to lurk < OE lutien, aki to lutan: see fol. ] a clumsy, stupid fellow; boor —vt. [Obs.] to tree with contempt; flout —lout'ish adj. —lout'ish||y adv. —lout'ish||v adv. —lout'ish||v

ness n.
lout? (lout) vi., vt. [ME louten < OE lutan: for IE base see LITTLE
[Now Chiefly Dial.] to bow or curtsy; stoop
Louth (louth) county in Leinster province, E Ireland: 317 sq. mi. (8:
sq. km); pop. 88,000
Lou-vain (loō van'; E loō vān') [ME luver < MFr lover < MDu lot
gallery (in a theater), akin to OHG louba: see LODGE] Fr. name
LEUVEN

r (-gō'ər) n. a person who attends th

ter in the round') n. ARENA THEATE arde, mid-20th-cent. drama made up ous, or pointless situations and diaexistential nature of self-isolation

< LL theatricus (< Gr theatrikos) 

performances of stage plays, esp

th sing. v.] the art of the theater 2 ical effect; histrionic actions, man-

n. [ < L Thebae (< Gr Thēbai), m Thebes [ a colorless, crystalline, btained from opium and used in

For a pula For a pula Egypt, on the Nile, on the site of ief city of ancient Boeotia, EC

 $\mathrm{odL} < L < \mathrm{Gr}\ th\bar{e}k\bar{e}$ , a case  $< \mathrm{IE}$   $> \mathrm{Do^1}$ ,  $L\ facere$  1 Bot. a spore any sheath or sac enclosing an overing of an insect pupa —the'-

eca; sheathed an sants (tā dän sän') [Fr] TEA

lat. & acc. of thu, THOU! I the 1 place of thou by the Friends d person singular [thee speaks

ale (< IE \*dhēlu < base \*dhē : see prec.) + -OL<sup>1</sup> old name for

h: see THIEF & -THI | the act or

ny the legal term for the unlawful ny the legal term for the unlawful perty without-his or her consent ierson of it; robbery in its strict of another's property from that ence by the use of violence or a a breaking into a house, with is often restricted to such an act

< thea see THEOPHYLLINE

pronominal adj. [ME theyr ive pron. replacing ME here, ade, or done by them: often ybody, somebody, everyone)

(see prec.) + es by analogy them: the absolute form of often after of la friend of better/: often used with a body, everyone) [he'll bring

belief in a god or gods 2 to PANTHEISM, POLYTHEISM I ruler of the universe and DEISM—the ist n., adj.

|| y adv. Selma || a feminine frame theim < ON, dat: of the ase of THEY: also used as a (that's them) ting a theme or themes 2

rd or to a vowel ending a
g 3 (Brit.) Philately of
r topic —n. [Brit.] any
cally adv.

the person being tested to so so all situations are cohological makeup of the poil 1.1 a) a topical topical and topical makeup of 1.1 a) a topical top

subject, as of a lecture, sermon, essay, etc. b) a recurring, unifying subject or idea; motif, often one used decoratively 2 a short essay, one written as an assignment in a school course 3 a) a short esp. one written as an assignment in a school course of a silver melody used as the subject of a musical composition b) a musical phrase upon which variations are developed \*4 short for THEME SONG -VI. themed, them'ing to give a theme to; specifi, to plan according to a central theme is themed restaurant. SYM. SUBJECT theme park an amusement park built around some central theme, as a land of fantasy, future world, or past age

as a land of tantasy, tuture world, or past age
wheme song 1 a recurring song or melody in a film, musical, etc.,
often one intended to set the mood, that becomes popularly identified with the work 2 an identifying song or melody used by a dance
band, singer, etc. or for a radio or television series; signature
The mis (the mis) Gr. Myth. a goddess of law and justice, daughter of
Uranus and Gaea: represented as holding aloft a scale for weighing

opposing ciains
The mis to cles (the mis te klez') c. 525-c. 460 B.C.; Athenian states

man & naval commander them selves (them selves, them-) pron. [Late (Northern) ME thairm them serves (them serves, them.) pron. Late (Northern) with that selfe for ME hemselve(n) (see THEY) + -s, pl. suffix 1 used with the 3d pers. pl. pronoun: a) as an intensive (they went themselves) b) as a reflexive (they hurt themselves) 2 their real or normal selves (they hurt themselves)

a reflexive (they hurt themselves] 2 their real or normal selves [they are not themselves today]
then (then) adv. [ME: see THAN] 1 at that time [he was young then]
2 soon afterward; next in time [he took his hat and then left] 3 next in order [first comes alpha and then beta] 4 in that case; therefore; accordingly: used with conjunctive force [fi it rains, then there will be no picnic] 5 besides; moreover [he likes to walk, and then it's good exercise] 6 at another time or at other times: used as a correlative with now, sometimes, etc. [now it's warm, then freezing]—adj. of that time, being such at that time [the then director]—n. that time [by then, they were gone]—but then but on the other hand; but at the same time—then and there at that time and in that place; at once—what then? what would happen in that case? Thenar (the nar (the nar) n. [ModL < Gr < IE base \*dhen. palm of the hand, level place > DEN] 1 the palm of the hand or, sometimes, the sole of the foot 2 the bulge at the base of the thumb—adj. of a thenar

thence (thens; also thens) adv. [ME thens, thannes (with adv. gen suffix es) < OE thanan, thence: for IE base see THAT Archaic from that place; therefrom 2 from that time; thenceforth 3 on that

account; therefore thence forth (-forth') adv. from that time onward; after that; there-

thence form ( form ) adv. from that time onward, after that, there-after Also thence for ward ( for word) theo. (the o, -a) [ < Gr theos, god < ? IE \*dhewes-, to storm, breathe > L furere, to rage [ combining form God or a god [theocentric]]

> L furere, to rage | combining form God or a god theocenary Also, before a vowel, the helo-bro-mine (the obro'men', -min) n. | < ModL Theobroma, a genus of trees of the sterculia family < Gr theos, god (see prec.) + broma, food + -INE<sup>3</sup> | a bitter, crystalline alkaloid, C-H<sub>8</sub>N<sub>1</sub>O<sub>3</sub> extracted from the leaves and seeds of the cacao plant, used in modicine as a directic and nerve stimulant: it is closely related to medicine as a diuretic and nerve stimulant: it is closely related to

imedicine as a divertic and nerve stimulant: it is closely related to caffeine and is also found in cola nuts and tea thelo-cen-tric (the o sen'trik) adj. [Theo + CENTRIC] centering on or directed toward God — the o-cen'trically adv. — the o-centric'lty (tris'a te) n.—the o-cen'trism (triz'am) n.

theocralcy (the ak'ra se) n. pl.—cies. [Gr theokratia: see theo-& aperson or persons claiming to rule with divine authority 3 a country governed in this way —theocrat (the okratia: see theo-cratfic of the o-cratfical adj.—the o-cratfically adv: The o-cratfical adj.—the o-cratfically adv: The o-cratfical adj.—the o-cratfically adv: The o-cratfical sed of sed on pl.—cies. [Fr theodice: coined by Leibniz (1710) < Gr theos, god + dike, justice] a system of natural theology saimed at seeking to vindicate divine justice in allowing evil to exist the odj. (ife the ad'o it') n. [Modd theodelitus: prob. invented (c. imahematician] a surveying instrument used to measure vertical and horizontal and the odd the order the odd.

ment used to measure vertical and horizontal angles —the od/o lit/ic ( ð lit'ik) *adj.* 

Thelo dorla (the'ə dôr'ə) [Gr Theodora see fol.] a feminine name: dim. Dora

Min. Dora

Theo-dore (the'ə dor') [L. Theodonis < Gr Theodoros < theos, god +
doron, gift ] a masculine name: dim.
Ted, Teddy; fem. Theodora Also

The odo-ric (the ad'e rik) LL The-odorics, altered (after Theodorics, Theodore) < Goth \*Thiudoreiks (thiuda, folk, akin to OHG thioda (see DEUTSCHLAND) + reiks, ruler, leader: for IE base see REGAL c. A.D. 454-526; king of the

ine oglo-ny (thể äg'ə nê) n., pl. -nies [Gr theogonia: see THEO- & secolony (the ag's ne) n., pl. -nies [Gr theogonia: see Theo & Gonic (see Theo see Theologian is dealer theologian 2 theological 3 theology see theologian 2 theologian 3 theology secologian theology or a theology a student of or secological (the's löj's), je so) n. [MFr théologien] a student of or secological (the's läj'i kel) adj. of, having to do with, based on, or

1387 theme park / therapy

offering instruction in, theology or a theology Also the o log/ic: the ologically adv.
the ological virtues Theol. the three virtues (faith, hope, and char's

ity) that have God as their immediate object

the olio gize (the al'a jiz') vt. -gized', -giz'ing to put into theological terms; fit into a theology —vt. to speculate theologically —the ol'o

giz'er n.

the-ol-olgy (the al'e) je) n., pl. -gies [ME theologie < LL(Ec) theologia < Gr: see THEO-&-LOGY] 1 the study of religious doctrines and matters of divinity; specif, the study of God and the relations between God, mankind, and the universe 2 a specific formulation or systemization of religious doctrine or belief as set forth by a given religion or denomination or by one or more individuals the-omja-chy (the am'e ke) n., pl. -chies [Gr theomachia see THEO-&-MACHY] 1 a battle against the gods 2 strife among the gods theomor-phic (the'o mor'fik) adj. [< Gr theomor-phos (see THEO-&-MORPH) + -IC] having the form, likeness, or aspect of God or a god —the'o-mor'phism n.

-MORPH) + -IC. having the form, likeness, or aspect of God or a god — the formor phism n.

the onlo-mous (the än's mas) adj. [ < THEO- + (AUTO)NOMOUS] controlled by God — the on formous | y adv. — the on formous | x Gr the ophania < Gr the ophania : see THEO- & -PHANE ] a manifestation of God or a deity theos (see THEO-) + phrazein, to speak, plan, observe, guard: hence, lit., ? divinely protected ] c. 372-c. 287 B.C.; Gr. philosopher & natural scientist

lit.,? divinely protected \$\[ c. 372-c. 287 B.C.;\$ Gr. philosopher & natural scientist thelo-phyl-line (the'o fil'en', -in) \$n. \$\[ \] \ ModL \$thea\$, tea (infl. by Gr. goddess, as being a divine herb, but < source of \$TEA\$) + -PHYLL + -INE^3 \] a colorless, crystalline alkaloid, \$C\_7H\_8N\_4O\_2\$. \$H\_2O\$, extracted from tea leaves or prepared synthetically: an isomer of theobyomine the-oribo (the \$\partial r^\*bo) \$n. \$pl. -bos \$\[ \] Fr théorbe < It tiorba < ? \$\[ \] a large 17th-cent. lute with a double neck and two sets of strings thelo-rem (the's ram, -rem') \$n. \$\[ \] < Fr or \$L. Fr. théorème < L. theorems < Gr theorems < theorems, to look at, view < theorems, spectator, for IE base see THEATER \$\[ \] 1 a proposition that is not self-evident but that can be proved from accepted premises and so is established as a law or principle \$2\$ an expression of relations in an equation or formula \$3\$ \$Math\$, \$Physics\$ a proposition embodying something to be proved —the'p-relmat'ic (-re mat'ik) \$adj\$. \$\[ \] (ine)-relical (the's ret' kal) \$adj\$. \$\[ \] < -AL \$\[ \] 1 of or constituting theory \$2\$ limited to or based on theory; not practical or applied; hypothetical \$3\$ tending to theorize; speculative Also the'p-rel'ical (the's ret' kal) \$n\$, a person who theorizes, esp. one who specializes in the theory of some art, science, etc. Also the'portials of theoretics (the's ret'iks) \$n.pt. [with sing. \$v.\$] the theoretical part of \$1 \text{leads} \$\]

thele retrics (the eret'iks) n.pl. [with sing v.] the theoretical part of a field of knowledge the orize (the orize) vi. -rized, -rizing to form a theory or theories;

thelo-rize (the'ə riz') vi.-rized, -riz'ing to form a theory or theories; speculate—the'o-riz'er n.—the'o-riza'tion n.
the'o-ry (the'ə rē, the'rē, thir'ē) n., pl.-ries [< Fr or LL: Fr theorie < LL theoria < Gr theoria, a looking at, contemplation, speculation, theory < theorem: see THEOREM [1 orig., a mental viewing; contemplation 2 a speculative idea or plan as to how something might be done 3 a systematic statement of principles involved (the theory of equations in mathematics) 4 a formulation of apparent relationships or underlying principles of certain observed phenomena which has been verified to some degree 5 that branch of an art or science consisting in a knowledge of its principles and methods rather than in its practice; pure, as opposed to applied, science, etc. 6 popularly. in its practice; pure, as opposed to applied, science, etc. 6 popularly,

in its practice; pure, as opposed to applied, science, etc. 6 popularly, a mere conjecture, or guess SYM.—theory, as compared here, implies considerable evidence in support of a formulated general principle explaining the operation of certain phenomena (the theory of evolution); hypothesis implies an inadequacy of evidence in support of an explanation that is tentatively inferred, often as a basis for further experimentation (the nebular hypothesis); law implies an exact formulation of the principle operating in a sequence of events in nature, observed to occur with unvarying uniformity under the same conditions (the law of the conservation of energy)

heory of games GAME THEORY

theory of games GAME THEORY
theosophy (the as's fe) n. [ML theosophia < LGr; knowledges of divine things < theosophos, wise in divine matters < Gr theos, god + sophos, wise is elimentally a religious or semireligious set of occult beliefs rejecting Judeo-Christian revelation and theology, often incorporating elements of Buddhism and Brahmanism, and held to be based on a special mystical insight or on superior speculation—the soph (ic -s af'ik) or the soph (ic ally adv.—the os oph (ic ally ad

adv.
theria peu-tics (ther's pyōōt'iks) n.pl. [with sing. v.] the branch of medicine that deals with the treatment and cure of diseases; therapy atheria-pist (ther's pist) n. a specialist in a certain form of therapy Also theria-peu'tist (-pyōōt'ist).

Also ther a peu tist (-pyoot ist)
ther a py (ther a pe) n., pl. -pies [ModL therapia < Gr therapeia <
therapeuein, to nurse, cure the treatment of disease or of any
physical or mental disorder by medical or physical means, usually

at, āte, cār; ten, ēve; is, ice; gō, hōrn, look, tōōl; oil, out; up, fer; ə for unstressed vowels, as a in ago, u in focus; 'as in Latin (lat'n); chin; she; zh as in azure (azh'ar); thin, the; ŋ as in ring (rin) fir etymologies: \* = unattested; < = derived from; > = from which = Americanism See inside front and back covers



TRANSIT THEODOLITE

## **Exhibit C – Jackson Declaration**

(CPG Sec. 440.100, Marketed New Drugs Without Approved NDAs and ANDAs)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

U.S. Food & Drug Administration

## Inspections, Compliance, Enforcement, and Criminal Investigations

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#### CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs

Guidance for FDA Staff and Industry<sup>1</sup>
Marketed Unapproved Drugs —
Compliance Policy Guide
Chapter 4
Subchapter 440

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

#### I. INTRODUCTION

This Compliance Policy Guide (CPG) describes how we intend to exercise our enforcement discretion with regard to drug marketed in the United States that do not have required FDA approval for marketing. This is a revision of a guidance of the same name that was issued in June 2006. The guidance has been revised to state that the enforcement priorities and potential exercise of enforcement discretion discussed in the guidance apply only to unapproved new drugs (including new drugs covered by the Over-the-Counter (OTC) Drug Review), except for licensed biologics and veterinary drugs, that are commercially used or sold<sup>2</sup> prior to September 19, 2011.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### II. BACKGROUND

#### A. Reason for This Guidance

For historical reasons, some drugs are available in the United States that lack required FDA approval for marketing. A brief, informal summary description of the various categories of these drugs and their regulatory status is provided in Appendix A as general background for this document. The manufacturers of these drugs have not received FDA approval to legally market their drugs, nor are the drugs being marketed in accordance with the OTC drug review. The new drug approval and OTC drug monograph processes play an essential role in ensuring that all drugs are both safe and effective for their intended uses. Manufacturers of drugs that lack required approval, including those that are not marketed in accordance with an OTC drug monograph, have not provided FDA with evidence demonstrating that their products are safe and effective, and so we have an interest in taking steps to either encourage the manufacturers of these products to obtain the required evidence and comply with th approval provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) or remove the products from the market. We want to achieve these goals without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market.

The goals of this guidance are to (1) clarify for FDA personnel and the regulated industry how we intend to exercis our enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval.

#### **B. Historical Enforcement Approach**

FDA estimates that in the United States today perhaps as many as several thousand drug products are marketed illegally without required FDA approval. Because we do not have complete data on illegally marketed products, and because the universe of such products is constantly changing as products enter and leave the market, we first have to identify illegally marketed products before we can contemplate enforcement action. Once an illegally

marketed product is identified, taking enforcement action against the product would typically involve one or more of the following: requesting voluntary compliance; providing notice of action in a Federal Register notice; issuing an untitled letter; issuing a Warning Letter; or initiating a seizure, injunction, or other proceeding. Each of these actions is time-consuming and resource intensive. Recognizing that we are unable to take action immediately against all of these illegally marketed products and that we need to make the best use of scarce Agency resources we have had to prioritize our enforcement efforts and exercise enforcement discretion with regard to products tha remain on the market.

In general, in recent years, FDA has employed a risk-based enforcement approach with respect to marketed unapproved drugs. This approach includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory follow-up. Some of the specific actions the Agency has taken have been precipitated by evidence of safety or effectiveness problems that has either come to our attention during inspections or been brought to our attention b outside sources.

#### III. FDA'S ENFORCEMENT POLICY

In the discussion that follows, we intend to clarify our approach to prioritizing our enforcement actions and exercising ou enforcement discretion with regard to unapproved, illegally marketed drug products.

The enforcement priorities and potential exercise of enforcement discretion discussed in this guidance apply only to unapproved drug products that are being commercially used or sold as of September 19, 2011. All unapproved drugs introduced onto the market after that date are subject to immediate enforcement action at any time, without prior notic and without regard to the enforcement priorities set forth below. In light of the notice provided by this guidance, we believe it is inappropriate to exercise enforcement discretion with respect to unapproved drugs that a company (includin a manufacturer or distributor) begins marketing after September 19, 2011.

For unapproved drugs commercially used or sold as of September 19, 2011, FDA's enforcement priorities are described below.

#### A. Enforcement Priorities

Consistent with our risk-based approach to the regulation of pharmaceuticals, FDA intends to continue its current policy of giving higher priority to enforcement actions involving unapproved drug products in the following categories:

*Drugs with potential safety risks.* Removing potentially unsafe drugs protects the public from direct and indirect health threats.

**Drugs that lack evidence of effectiveness.** Removing ineffective drugs protects the public from using these products in lieu of effective treatments. Depending on the indication, some ineffective products would, of course, pose safety risks as well.

Health fraud drugs. FDA defines health fraud as "[t]he deceptive promotion, advertisement, distribution or sale of articles . . . that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes. Such practices may be deliberate or done without adequate knowledge or understanding of the article" (CPG Sec. 120.500). Of highest priority in this area are drugs that present a direct risk to health. Indirect health hazards exist if, as a result of reliance on the product, the consumer is likely to delay or discontinue appropriate medical treatment. Indirect health hazards will be evaluated for enforcement action based on section 120.500, Health Fraud - Factors in Considering Regulatory Action (CPG Sec. 120.500). FDA's health fraud CPG outlines priorities for evaluating regulatory actions against indirect health hazard products, such as whether the therapeutic claims are significant, whether there are any scientific data to support the safety and effectiveness of the product, and the degree of vulnerability of the prospective user group (CPG Sec. 120.500).

Drugs that present direct challenges to the new drug approval and OTC drug monograph systems. The drug approval and OTC drug monograph systems are designed to avoid the risks associated with potentially unsafe, ineffective, and fraudulent drugs. The drugs described in the preceding three categories present direct challenges to these systems, as do unapproved drugs that directly compete with an approved drug, such as when company obtains approval of a new drug application (NDA) for a product that other companies are marketing without approval (see section III.C, Special Circumstances – Newly Approved Product). Also included are drugs marketed in violation of a final and effective OTC drug monograph. Targeting drugs that challenge the drug approval or OTC drug monograph systems buttresses the integrity of these systems and makes it more likely that firms will comply with the new drug approval and monograph requirements, which benefits the public health.

Unapproved new drugs that are also violative of the Act in other ways. The Agency also intends, in circumstances that it considers appropriate, to continue its policy of enforcing the preapproval requirements of the FD&C Act against a drug or firm that also violates another provision of the FD&C Act, even if there are other unapproved versions of the drug made by other firms on the market. For instance, if a firm that sells an unapproved new drug also violates current good manufacturing practice (CGMP) regulations, the Agency is not inclined to limit an enforcement action in that instance to the CGMP violations. Rather, the Agency may initiate a regulatory action that targets both the CGMP violation and the violation of section 505 of the FD&C Act (21 U.S.C. 355). This policy efficiently preserves scarce Agency resources by allowing the Agency to pursue all applicable

charges against a drug and/or a firm and avoiding duplicative action. See *United States v. Sage Pharmaceuticals, Inc.*, 210 F.3d 475, 479-80 (5th Cir. 2000).

Drugs that are reformulated to evade an FDA enforcement action. The Agency is also aware of instances in which companies that anticipate an FDA enforcement action against a specific type or formulation of an unapprove product have made formulation changes to evade that action, but have not brought the product into compliance with the law. Companies should be aware that the Agency is not inclined to exercise its enforcement discretion wit regard to such products. Factors that the Agency may consider in determining whether to bring action against the reformulated products include, but are not limited to, the timing of the change, the addition of an ingredient without adequate scientific justification (see, for example, 21 CFR 300.50 and 330.10(a)(4)(iv)), the creation of a new combination that has not previously been marketed, and the claims made for the new product.

#### B. Notice of Enforcement Action and Continued Marketing of Unapproved Drugs

FDA is not required to, and generally does not intend to, give special notice that a drug product may be subject to enforcement action, unless FDA determines that notice is necessary or appropriate to protect the public health.4 The issuance of this guidance is intended to provide notice that any product that is being marketed illegally is subject to FDA enforcement action at any time.<sup>5</sup> The only exception to this policy is, as set forth elsewhere, that generally products subject to an ongoing DESI for proceeding or ongoing OTC drug monograph proceeding (i.e., an OTC product that is part of the OTC drug review for which an effective final monograph is not yet in place) may remain on the market during the pendency of that proceeding and any additional period specifically provided in the proceeding (such as a delay in the effective date of a final OTC drug monograph). However, once the relevant DESI or OTC drug monograph proceeding is completed and any additional grace period specifically provided in the proceeding has expired, all products that are not in compliance with the conditions for marketing determined in that proceeding are subject to enforcement action at any time without further notice (see, for example, 21 CFR 310.6).

FDA intends to evaluate on a case-by-case basis whether justification exists to exercise enforcement discretion to allow continued marketing for some period of time after FDA determines that a product is being marketed illegally In deciding whether to allow such a grace period, we may consider the following factors: (1) the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug); (2) the difficulty associated with conducting any required studies, preparing and submitting applications, and obtaining approval of an application; (3) the burden on affected parties of immediately removing the products from the market; (4) the Agency's available enforcement resources; and (5) any special circumstances relevant to the particular case under consideration. However, as stated above, FDA does not intend to apply any such grace period to an unapproved drug that was introduced onto the market after September 19, 2011.

#### C. Special Circumstances — Newly Approved Product

Sometimes, a company may obtain approval of an NDA for a product that other companies are marketing without approval. <sup>10</sup> We want to encourage this type of voluntary compliance with the new drug requirements because it benefits the public health by increasing the assurance that marketed drug products are safe and effective — it also reduces the resources that FDA must expend on enforcement. Thus, because they present a direct challenge to the drug approval system, FDA is more likely to take enforcement action against remaining unapproved drugs in this kind of situation. However, we intend to take into account the circumstances once the product is approved in determining how to exercise our enforcement discretion with regard to the unapproved products. In exercising enforcement discretion, we intend to balance the need to provide incentives for voluntary compliance against the implications of enforcement actions on the marketplace and on consumers who are accustomed to using the marketed products.

When a company obtains approval to market a product that other companies are marketing without approval, FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (e.g., seizure or injunction) against marketed unapproved products of the same type. However, the grace period provided is expected to vary from this baseline based upon the following factors: (1) th effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of the holder of the approved application to meet the needs of patients taking the drug); (2) whether the effort to obtain approval was publicly disclosed; (3) the difficulty associated with conducting any required studies, preparing and submitting applications, and obtaining approval of an application; (4) the burden on affected parties of removing the products from the market; (5) the Agency's available enforcement resources; and (6) any other special circumstances relevant to the particular case under consideration. To assist in an orderly transition to the approved product(s), in implementing a grace period, FDA may identify interim dates by which firms should first cease manufacturing unapproved forms of the drug product, and later cease distributing the unapproved product.

The length of any grace period and the nature of any enforcement action taken by FDA will be decided on a case-by-case basis. Companies should be aware that a Warning Letter may not be sent before initiation of enforcement action and should not expect any grace period that is granted to protect them from the need to leave

the market for some period of time while obtaining approval. Companies marketing unapproved new drugs should also recognize that, while FDA normally intends to allow a grace period of roughly 1 year from the date of approve of an unapproved product before it will initiate enforcement action (e.g., seizure or injunction) against others who are marketing that unapproved product, it is possible that a substantially shorter grace period would be provided, depending on the individual facts and circumstances. 12

The shorter the grace period, the more likely it is that the first company to obtain an approval will have a period of defacto market exclusivity before other products obtain approval. For example, if FDA provides a 1-year grace period before it takes action to remove unapproved competitors from the market, and it takes 2 years for a secon application to be approved, the first approved product could have 1 year of market exclusivity before the onset of competition. If FDA provides for a shorter grace period, the period of effective exclusivity could be longer. FDA hopes that this period of market exclusivity will provide an incentive to firms to be the first to obtain approval to market a previously unapproved drug. <sup>13</sup>

#### D. Regulatory Action Guidance

District offices are encouraged to refer to CDER for review (with copies of labeling) any unapproved drugs that appear to fall within the enforcement priorities in section III.A. Charges that may be brought against unapproved drugs include, but are not limited to, violations of 21 U.S.C. 355(a) and 352(f)(1) of the FD&C Act. Other charges may also apply based on, among others, violations of 21 U.S.C. 351(a)(2)(B) (CGMP), 352(a) (misbranding), or 352(o) (failure to register or list).

#### **APPENDIX**

# BRIEF HISTORY OF FDA MARKETING APPROVAL REQUIREMENTS AND CATEGORIES OF DRUGS THAT LACK REQUIRED FDA APPROVAL<sup>14</sup>

Key events in the history of FDA's drug approval regulation and the categories of drugs affected by these events are described below.

#### A. 1938 and 1962 Legislation

The original Federal Food and Drugs Act of June 30, 1906, first brought drug regulation under federal law. That Act prohibited the sale of adulterated or misbranded drugs, but did not require that drugs be approved by FDA. In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which required that new drugs be approved for safety. As discussed below, the active ingredients of many drugs currently on the market were first introduced, at least in some form, before 1938. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS) to the approved drug to be covered by that approval, and allowed those IRS drugs to be marketed without independent approval. Many manufacturers also introduced drugs onto the market between 1938 and 1962 based on their own conclusion that the products were generally recognized as safe (GRAS) or based on an opinion from FDA that the products were not new drugs. Between 1938 and 1962, the Agency issued many such opinions although all were formally revoked in 1968 (see 21 CFR 310.100).

#### B. DESI

In 1962, Congress amended the Act to require that a new drug also be proven effective, as well as safe, to obtain FDA approval. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962 through the new drug approval process.

FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that were approved only for safety between 1938 and 1962. The NAS/NRC created 30 panels of 6 professionals each to conduct the review, which was broken down into specific drug categories. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and re-evaluated the findings of each panel and published its findings in *Federal Register* notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the 3,400 products specifically reviewed by the NAS/NRCs as well as the even larger number of IRS products that entered the market without FDA approval.

Because DESI products were covered by approved (pre-1962) applications, the Agency concluded that, prior to removing products not found effective from the market, it would follow procedures in the FD&C Act and regulations that apply when an approved new drug application is withdrawn:

- All initial DESI determinations are published in the Federal Register and, if the drug is found to be less than fully
  effective, there is an opportunity for a hearing.
- The Agency considers the basis of any hearing request and either grants the hearing or denies the hearing on summary judgment and publishes its final determination in the Federal Register.
- If FDA's final determination classifies the drug as effective for its labeled indications, as required by the FD&C Act,
  FDA still requires approved applications for continued marketing of the drug and all drugs IRS to it NDA
  supplements for those drugs with NDAs approved for safety, or new ANDAs or NDAs, as appropriate, for IRS drugs

DESI-effective drugs that do not obtain approval of the required supplement, ANDA, or NDA are subject to enforcement action.

• If FDA's final determination classifies the drug as ineffective, the drug and those IRS to it can no longer be marketed and are subject to enforcement action.

#### 1. Products Subject to Ongoing DESI Proceedings

Some unapproved marketed products are undergoing DESI reviews in which a final determination regarding efficacy has not yet been made. In addition to the products specifically reviewed by the NAS/NRC (i.e., those products approved for safety only between 1938 and 1962), this group includes unapproved products identical, related, or similar to those products specifically reviewed (see 21 CFR 310.6). In virtually all these proceedings, FDA has made an initial determination that the products lack substantial evidence of effectiveness, and the manufacturers have requested a hearing on that finding. It is the Agency's longstanding policy that products subject to an ongoing DESI proceeding may remain on the market during the pendency of the proceeding. See, e.g., *Upjohn Co. v. Finch*, 303 F. Supp. 241, 256-61 (W.D. Mich. 1969). 15

#### 2. Products Subject to Completed DESI Proceedings

Some unapproved marketed products are subject to already-completed DESI proceedings and lack required approved applications. This includes a number of products IRS to DESI products for which approval was withdrawn due to a lack of substantial evidence of effectiveness. This group also includes a number of products IRS to those DESI products for whic FDA made a final determination that the product is effective, but applications for the IRS products have not been both submitted and approved as required under the statute and longstanding enforcement policy (see 21 CFR 310.6). FDA considers all products described in this paragraph to be marketed illegally.

#### C. Prescription Drug Wrap-Up

As mentioned above, many drugs came onto the market before 1962 without FDA approvals. Of these, many claimed to have been marketed prior to 1938 or to be IRS to such a drug. Drugs that did not have pre-1962 approvals and were no IRS to drugs with pre-1962 approvals were not subject to DESI. For a period of time, FDA did not take action against these drugs and did not take action against new unapproved drugs that were IRS to these pre-1962 drugs that entered the market without approval.

Beginning in 1983, it was discovered that one drug that was IRS to a pre-1962 drug, a high potency Vitamin E intravenous injection named E-Ferol, was associated with adverse reactions in about 100 premature infants, 40 of whom died. In November of 1984, in response to this, a congressional oversight committee issued a report to FDA expressing the committee's concern regarding the thousands of unapproved drug products in the marketplace.

In response to the E-Ferol tragedy, CDER assessed the number of pre-1962 non-DESI marketed drug products. To address those drug products, the Agency significantly revised and expanded CPG section 440.100 to cover all marketed unapproved prescription drugs, not just DESI products. The program for addressing these marketed unapproved drugs and certain others like them became known as the Prescription Drug Wrap-Up. Most of the Prescription Drug Wrap-Up drugs first entered the market before 1938, at least in some form. For the most part, the Agency had evaluated neither the safety nor the effectiveness of the drugs in the Prescription Drug Wrap-Up.

A drug that was subject to the Prescription Drug Wrap-Up is marketed illegally, unless the manufacturer of such a drug can establish that its drug is grandfathered or otherwise not a new drug.

Under the 1938 grandfather clause (see 21 U.S.C. 321(p)(1)), a drug product that was on the market prior to passage of the 1938 Act and which contained in its labeling the same representations concerning the conditions of use as it did prior to passage of that act was not considered a new drug and therefore was exempt from the requirement of having an approved new drug application.

Under the 1962 grandfather clause, the FD&C Act exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the FD&C Act at that time, and (c) not covered by an effective application. See Public Law 87-781, section 107 (reprinted following 21 U.S.C.A. 321); see also USV Pharmaceutical Corp. v. Weinberger, 412 U.S. 655, 662-66 (1973).

The two grandfather clauses in the FD&C Act have been construed very narrowly by the courts. FDA believes that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion. See 21 CFR 314.200(e)(5); see also *United States v. An Article of Drug (Bentex Ulcerine)*, 469 F.2d 875, 878 (5th Cir. 1972); *United States v. Articles of Drug Consisting of the Following: 5,906 Boxes*, 745 F.2d 105, 113 (1st Cir 1984).

Finally, a product would not be considered a new drug if it is generally recognized as safe and effective (GRAS/GRAE) an has been used to a material extent and for a material time. See 21 U.S.C. 321(p)(1) and (2). As with the grandfather clauses, this has been construed very narrowly by the courts. See, e.g., *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); *United States v. 50 Boxes More or Less Etc.*, 909 F.2d 24, 27-28 (1st Cir. 1990); *United States v. 225 Cartons . . . Fiorinal*, 871 F.2d 409 (3rd Cir. 1989). See also Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA, to Gary D. Dolch, Melvin Spigelman, and Jeffrey A. Staffa, Knoll Pharmaceutical Co. (April 26, 2001) (on file in FDA Docket No. 97N-0314/CP2) (finding that Synthroid, a levothyroxine sodium product, was not

#### GRAS/GRAE).

As mentioned above, the Agency believes it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a *new drug*. However, the Agency recognizes that it is at least theoretically possible. No part of this guidance, including the Appendix, is a finding as to the legal status of any particular drug product. In light of the strict standards governing exceptions to the approval process, it would be prudent for firms marketing unapprove products to carefully assess whether their products meet these standards.

#### D. New Unapproved Drugs

Some unapproved drugs were first marketed (or changed) after 1962. These drugs are on the market illegally. Some also may have already been the subject of a formal Agency finding that they are new drugs. See, e.g., 21 CFR 310.502 (discussing, among other things, controlled/timed release dosage forms).

#### E. Over-the-Counter (OTC) Drug Review

Although OTC drugs were originally included in DESI, FDA eventually concluded that this was not an efficient use of resources. The Agency also was faced with resource challenges because it was receiving many applications for different OTC drugs for the same indications. Therefore, in 1972, the Agency implemented a process of reviewing OTC drugs through rulemaking by therapeutic classes (e.g., antacids, antiperspirants, cold remedies). This process involves convening an advisory panel for each therapeutic class to review data relating to claims and active ingredients. These panel reports are then published in the *Federal Register*, and after FDA review, tentative final monographs for the classes of drugs are published. The final step is the publication of a final monograph for each class, which sets forth the allowable claims, labeling, and active ingredients for OTC drugs in each class (see, e.g., 21 CFR part 333). Drugs marketed in accordance with a final monograph are considered to be generally recognized as safe and effective (GRAS/GRAE) and do not require FDA approval of a marketing application.

Final monographs have been published for the majority of OTC drugs. Tentative final monographs are in place for virtually all categories of OTC drugs. FDA has also finalized a number of *negative monographs* that list therapeutic categories (e.g., OTC daytime sedatives, 21 CFR 310.519) in which no OTC drugs can be marketed without approval. Finally, the Agency has promulgated a list of active ingredients that cannot be used in OTC drugs without approved applications because there are inadequate data to establish that they are GRAS/GRAE (e.g., phenolphthalein in stimulan laxative products, 21 CFR 310.545(a)(12)(iv)(B)).

OTC drugs covered by ongoing OTC drug monograph proceedings may remain on the market as provided in current enforcement policies (see, e.g., CPG sections 450.200 and 450.300, and 21 CFR part 330). This document does not affec the current enforcement policies for such drugs.

OTC drugs that need approval, either because their ingredients or claims are not within the scope of the OTC drug review or because they are not allowed under a final monograph or another final rule, are illegally marketed. For example, this group would include a product containing an ingredient determined to be ineffective for a particular indication or one tha exceeds the dosage limit established in the monograph. Such products are new drugs that must be approved by FDA to be legally marketed.

- <sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.
- <sup>2</sup> For the purposes of this guidance, the term "commercially used or sold" means that the product has been used in a business or activity involving retail or wholesale marketing and/or sale.
- <sup>3</sup> This rough estimate comprises several hundred drugs (different active ingredients) in various strengths, combinations, and dosage forms from multiple distributors and repackagers.
- <sup>4</sup> For example, in 1997, FDA issued a Federal Register notice declaring all orally administered levothyroxine sodium products to be new drugs and requiring manufacturers to obtain approved new drug applications (62 FR 43535, August 14, 1997). Nevertheless, FDA gave manufacturers 3 years (later extended to 4 (65 FR 24488, April 26, 2000)) to obtain approved applications and allowed continued marketing without approved new drug applications because FDA found that levothyroxine sodium products were medically necessary to treat hypothyroidism and no alternative drug provided an adequate substitute.
- <sup>5</sup> For example, FDA may take action at any time against a product that was originally marketed before 1938, but that has been changed since 1938 in such a way as to lose its grandfather status (21 U.S.C. 321(p)).
- <sup>6</sup> The Drug Efficacy Study Implementation (DESI) was the process used by FDA to evaluate for effectiveness for their labeled indications over 3,400 products that were approved only for safety between 1938 and 1962. DESI is explained more fully in the appendix to this document.
- <sup>7</sup> OTC drugs covered by ongoing OTC drug monograph proceedings may remain on the market as provided in current enforcement policies. See, for example, CPG sections 450.200 and 450.300 and 21 CFR part 330. This document does not affect the current enforcement policies for such drugs.
- <sup>8</sup> Sometimes, a final OTC drug monograph may have a delayed effective date or provide for a specific period of time for marketed drugs to come into compliance with the monograph. At the end of that period, drugs that are not marketed in accordance with the monograph are subject to enforcement action and the exercise of enforcement discretion in the

same way as any other drug discussed in this CPG.

- <sup>9</sup> For purposes of this guidance, the terms grace period and allow a grace period refer to an exercise of enforcement discretion by the Agency (i.e., a period of time during which FDA, as a matter of discretion, elects not to initiate a regulatory action on the ground that an article is an unapproved new drug).
- <sup>10</sup> These may be products that are the same as the approved product or somewhat different, such as products of different strength.
- <sup>11</sup> For example, at the Agency's discretion, we may provide for a shorter grace period if an applicant seeking approval o a product that other companies are marketing without approval agrees to publication, around the time it submits the approval application, of a Federal Register notice informing the public that the applicant has submitted that application. I shortened grace period may also be warranted if the fact of the application is widely known publicly because of applicant press releases or other public statements. Such a grace period may run from the time of approval or from the time the applicant has made the public aware of the submission, as the Agency deems appropriate.
- <sup>12</sup> Firms are reminded that this CPG does not create any right to a grace period; the length of the grace period, if any, is solely at the discretion of the Agency. For instance, firms should not expect any grace period when the public health requires immediate removal of a product from the market, or when the Agency has given specific prior notice in the Federal Register or otherwise that a drug product requires FDA approval.
- <sup>13</sup> The Agency understands that, under the Act, holders of NDAs must list patents claiming the approved drug product and that newly approved drug products may, in certain circumstances, be eligible for marketing exclusivity. Listed patents and marketing exclusivity may delay the approval of competitor products. If FDA believes that an NDA holder is manipulating these statutory protections to inappropriately delay competition, the Agency will provide relevant information on the matter to the Federal Trade Commission (FTC). In the past, FDA has provided information to the FTC regarding patent infringement lawsuits related to pending abbreviated new drug applications (ANDAs), citizen petitions, and scientific challenges to the approval of competitor drug products.
- <sup>14</sup> This brief history document should be viewed as a secondary source. To determine the regulatory status of a particular drug or category of drugs, the original source documents cited should be consulted.
- 15 Products first marketed after a hearing notice is issued with a different formulation than those covered by the notice are not considered subject to the DESI proceeding. Rather, they need approval prior to marketing. Under longstanding Agency policies, a firm holding an NDA on a product for which a DESI hearing is pending must submit a supplement prior to reformulating that product. The changed formulation may not be marketed as a related product under the pending DESI proceeding; it is a new drug, and it must be approved for safety and efficacy before it can be legally marketed. See, e.g., "Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy" (DESI 6514), 49 FR 153 (January 3, 1984) (Dimetane and Actifed); "Certain Drugs Containing Antibiotic, Corticosteroid, and Antifungal Components" (DESI 10826), 50 FR 15227 (April 17, 1985) (Mycolog). See also 21 U.S.C. 356a(c)(2)(A). Similarly, firms without NDAs cannot market new formulations of a drug without first getting approval of an NDA.

#### Links on this page:

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U.S Department of Health & Human Services

Links on this page:

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# **Exhibit D – Jackson Declaration**

(Slides from Program of the Twenty-First Annual Joint Patent Practice Seminar, April 21, 2005)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514 Novartis Pharmaceuticals Corp. v.
Eon Labs Manufacturing, Inc.

Federal Circuit:
- Is the term "hydrosol" limited to medicinal products prepared outside the body or does it include products formed in a patient's stomach upon ingestion of a pharmaceutical product.

DARBY &

Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.

- Federal Circuit defined 5 terms in 5 dictionaries to decide the meaning of the term "hydrosol" in claim 1.
- Webster's Third New International Dictionary (2002):
  - Hydrosol is "a sol in which the liquid is water."

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Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.

- FISHING EXPEDITION
- Dissent Judge Clevinger
  - \_"hydrosol" was not ambiguously defined
  - -"a sol in which the liquid is water"
  - does not require the hydrosol to be prepared outside of the body

Intellectual Property L Since 1895

DARBY &

Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.

- Take away for practitioners:
- Use CAUTION in patent drafting, particularly in describing pharmaceutical formulations
- Define pharmaceutical compositions as those capable of being formed outside the body or within the body after ingestion.

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Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.

- Would the outcome have been different under *Phillips v. AWH Corp.* (Fed. Cir. July 21, 2004)?
- Pending case on use of dictionary definitions to determine ordinary meaning of disputed term lacking explicit definition in specification
- Should dictionary meanings be a primary focus of claim construction????

Intellectual Property Since 1895

# **Exhibit E – Jackson Declaration**

(Screen Shot of the website http://www.cetaphil.com/ products/restoraderm-moisturizer)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

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# **PUBLIC**

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DERMATOLOGIST
AND PEDIATRICIAN
RECOMMENDED
BRAND OF CLEANSERS
AND MOISTURIZERS



WHERE TO BUY

# Cetaphil<sup>®</sup> RESTORADERM<sup>®</sup> Skin Restoring Moisturizer

10 fl oz

Like <149

WHERE TO BUY

Long lasting moisture for eczema-prone skin.

**CONTACT US** 

Cetaphil® RESTORADERM® Skin Restoring Moisturizer is suited for anyone three months of age and older with dry, itchy skin symptoms commonly associated with eczema or atopic-dermatitis. Best used after cleansing with RESTORADERM® Skin Restoring Body Wash, this effective moisturizer with patented Filaggrin technology™ and ceramide technology is formulated to hydrate and soothe very dry, atopic skin.

Developed to help replenish and protect the skin's natural moisture barrier, this nourishing skin moisturizer offers gentle yet effective hydration for dry, itchy skin. Free of fragrances, parabens and nut oils, Cetaphil® RESTORADERM® Skin Restoring Moisturizer is easily absorbed and restores moisture to help repair the skin's barrier. Use as part of a dermatologist-recommended, daily skin care routine for the management of eczema.

The NEA has awarded the Seal of Acceptance to Cetaphil® RESTORADERM® Skin Restoring Moisturizer. The Na ional Eczema Association (NEA) Seal of Acceptance is awarded to products that have been created or intended for use by persons with eczema or severe sensitive skin conditions and have satisfied the NEA Seal of Acceptance Criteria. Read the label to determine if this product may contain ingredients that may be unsuitable for your skin.

REVEWS CONSIDER USING WITH NGREDIENTS SPECIAL INSTRUCTIONS

For use after cleansing wi h Cetaphil<sup>®</sup> RESTORADERM<sup>®</sup> Skin Restoring Body Wash, it restores moisture to help repair the skin's barrier as part of a dermatologist-recommended, daily skin care routine for the management of eczema. Our Moisturizer and Body Wash work together to form a gentle daily skin care routine that helps soothe itch, and reduce he redness, dryness and irritation of eczema-prone skin. Both skin care products are clinically proven to be suitable for total-body use and are appropriate for ages three months and older.

GALDERMA

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# Exhibit F – Jackson Declaration

(Screen Shot of the website http://www.nationaleczema.org/living-with-eczema/bathing-moisturizing)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514





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Home » Living With Eczema » Education Resource Center » Skin Care

# **BATHING & MOISTURIZING**

# WHAT IS ECZEMA?

Eczema is a chronic recurring skin disorder that results in dry, easily irritated, itchy skin. There is no cure for eczema, but good daily skin care is essential to controlling the disease.

# WHAT ARE THE CHARACTERISTICS OF DRY SKIN?

When your skin is dry, it is not because it lacks grease or oil, but because it fails to retain water. For this reason, a good daily skin care regimen focuses on the basics of bathing and moisturizing.



Cetaphil® is the proud sponsor of the Bathing & Moisturizing website section.

All content controlled by the National Eczema Association.

### WHAT OTHER FACTORS CREATE DRY SKIN?

Wind, low humidity, cold temperature, excessive washing without use of moisturizers, and use of harsh, drying soaps can all cause dry skin and aggravate eczema.

### HOW DO I TAKE CARE OF MY DRY SKIN?

The most important treatment for dry skin is to put water back in it. The best way to get water into your skin is to briefly soak in a bath or shower and to moisturize immediately afterwards.

Use of an effective moisturizer several times every day improves skin hydration and barrier function. Moisturizer should be applied to the hands every time they are washed or in contact with water.

The goal of bathing and moisturizing is to help heal the skin. To repair the skin, it is necessary to decrease water loss.

Some dermatologists recommend that you perform your bathing and moisturizing regime at night just before going to bed. You are unlikely to further dry out or irritate your skin while sleeping, so the water can be more thoroughly absorbed into your skin.

If you have hand eczema dermatologists recommend that you soak your hands in water, apply prescription medications and moisturizer (preferably an oinment), and put on pure cotton gloves before going to sleep.

### IF I AM ON PRESCRIPTION DRUGS FOR MY ECZEMA, DO I STILL NEED TO MOISTURIZE?

Basic skin care can enhance the effect of prescription drugs, and it can prevent or minimize the severity of eczema relapse.

# WHAT ARE THE BASICS OF BATHING & MOISTURIZING?

TAKE AT LEAST ONE BATH OR SHOWER PER DAY. Use warm, not hot, water for at least 10 to 15 minutes. Avoid scrubbing your skin with a washcloth.

USE A GENTLE CLEANSING BAR OR WASH, NO SOAP. During a severe flare, you may choose to limit the use of cleansers to avoid possible irritation.

WHILE YOUR SKIN IS STILL WET (within three minutes of taking a bath or shower), apply any special skin medications prescribed for you and then liberally apply a moisturizer. This will seal in the water and make the skin less dry and itchy.

BE SURE TO APPLY ANY SPECIAL SKIN MEDICATIONS TO AREAS AFFECTED WITH ECZEMA BEFORE MOISTURIZING. The most common skin medications used to treat skin inflammation are prescription and non-prescription topical steroids or prescription topical immunomodulators (TIMS). Be sure to use these medications as directed. Remember that TIMS can sting if applied to wet skin, so apply a thin coat to affected areas only.

BE SURE TO APPLY MOISTURIZER ON ALL AREAS OF YOUR SKIN WHETHER IT HAS OR HAS NOT BEEN TREATED WITH MEDICATION. Specific occlusives or moisturizers may be individually recommended for you.

MOISTURIZERS ARE AVAILABLE IN MANY FORMS. Creams and ointments are more beneficial than lotions. Petroleum jelly is a good occlusive preparation to seal in the water; however, since it contains no water it works best after a soaking bath.

### **HOW DOES WATER HELP MY SKIN?**

- Water hydrates the stratum corneum (the top layer of skin).
- · Water softens skin so the topical medications and moisturizers can be absorbed.

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# BROWSE THIS

By Category
By Glossary

TAKE ACTION



SPECIAL EVENTS





# **PUBLIC**

- · Water removes allergens and irritants.
- Water cleanses, debrides, and removes crusted tissue.
- · Water is relaxing and reduces stress.

### IS WATER AN IRRITANT OR A TREATMENT?

Water IRRITATES skin IF...

- Skin is frequently wet without the immediate application of an effective moisturizer.
- Moisture evaporates, causing the skin barrier to become dry and irritated.

Water HYDRATES skin IF...

- After skin is wet, an effective moisturizer is applied within 3 minutes.
- Hydration is retained, keeping the skin barrier intact and flexible.

### WHAT ARE SOME CLEANSING TIPS?

- Gently cleanse your skin each day.
- Use mild, non-soap cleansers.
- Use fragrance-free, dye-free, low-pH (less than 5.5) cleansing products.
- Moisturize immediately after cleansing while your skin is still wet.
- · Avoid scrubbing with a washcloth or towel; pat instead.

# WHAT CLEANSING PRODUCT SHOULD I USE?

Our skin surface is much more acidic than soap: the average pH of soap is 9-10.5 while the normal pH of skin is 4-5.5. Some non-soap cleansers are specially formulated with a lower pH to be less irritating. Following are a few suggestions:

- Aquaphor® Gentle Wash & Shampoo
- AVEENO® Baby Cleansing Therapy Moisturizing Wash
- Basis® Sensitive Skin Bar
- · Bella Dry Skin Formula Moisturizing Body Bar
- CeraVe<sup>™</sup> Hydrating Cleanser
- Cetaphil® Restoraderm® Body Wash
- Cetaphil® Gentle Skin Cleanser
- Dove® Sensitive Skin Unscented Beauty Bar
- Eucerin® Calming Body Wash
- Exederm® Cleansing Wash
- Kiss of Nature Oh My Baby!! Moisturizing Castile Body Bar
- Mustela® Stelatopia Cream Cleanser
- MD Moms® Baby Silk Gentle All-Over Clean Hair & Body Wash
- · Oilatum® Cleansing Bar
- Vanicream<sup>™</sup> Cleansing Bar or Free & Clear Liquid Cleanse

# WHAT DOES CLEANSING REMOVE?

- Sebum (an oily substance produced by certain glands in the skin)
- Apocrine and eccrine secretions (skin gland secretions, discarded cells)
- Environmental dirt
- Bacteria, fungus, yeast and other germs
- Desquamated keratinocytes (dead skin cells that are the normal product of skin maturation)
- · Cosmetics, skin care products, medications

# WHAT IS PREFERABLE, A BATH OR A SHOWER? FOR HOW LONG?

Either a bath or shower (about 10-15 minutes long) will keep the skin from drying out.

DO NOT rub your skin.

**DO NOT** completely dry your skin after your shower or bath. Instead, pat yourself lightly with a towel if needed.

### WHAT TYPE OF BATH SHOULD I TAKE?

A soak in a tub of lukewarm water for 10–15 minutes will help the skin absorb water. You may wish to try one of the following for specific treatment:

**BLEACH BATHS:** Bleach baths make the tub into a swimming pool! Soak for about 10 minutes and rinse off. Use 2-3 times a week. Bleach baths decrease the bacteria on the skin and decrease bacterial skin infections. Use  $\frac{1}{2}$  cup household bleach for a full bathtub,  $\frac{1}{2}$  cup for a half bath.

VINEGAR BATHS: Add one cup to one pint of vinegar to the bath. Can be used as a wet

# ARTICLES/ RESEARCH

Moisturizing and Bathing Tips to Help Manage and Soothe Your Eczema

Everyday Skin Care: Maintaining Skin Integrity and Avoiding Inflammation

# ASK THE DOCTOR/EXPERTS

Bleach Baths for Babys?

Bleach Alternative?

**Bleach Baths** 

What else should I do for 7-month old Baby?

# SCRATCH PAD

Chlorinated Swimming Pool Helped

<u>Daughter's Eczema:</u> <u>Combination of Products</u>

12-Year-Old Son: Warm Tub & Aquaphor

Cider Vinegar Warm Bath

Aveeno and Cotton Dacron Blends

1 <u>2</u> <u>3</u> <u>next</u> <u>last</u>

### OTHER

Video: Starting From Scratch

<u>Seal of Acceptance: Product</u> <u>Directory - Personal Care</u>

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dressing too as it kills bacteria.

**BATH OIL BATHS:** Oils in the bath are a favorite of some providers and patients. Bath oils can leave the tub slippery—be careful. They can also leave a hard-to-clean film. See if they work for you.

**SALT BATHS:** When there is a significant flare the bath water may sting or be uncomfortable. Add one cup of table salt to the bath water to decrease this side effect.

BAKING SODA BATHS: Baking soda added to a bath or made into a paste can be used to relieve the itching.

OATMEAL BATHS: Oatmeal added to a bath or made into a paste can be used to relieve the itching.



# WHAT DOES MOISTURIZING DO?

Moisturizing improves skin hydration and barrier function.

Moisturizers are more effective when applied to skin that has been soaked in water.

### WHAT ARE THE DIFFERENT KINDS OF MOISTURIZERS?

There are three basic classes of moisturizers:

**OINTMENTS** are semi-solid greases that help to hydrate the skin by preventing water loss. Petroleum jelly has no additional ingredients, whereas other ointments contain a small proportion of water or other ingredients to make the ointment more spreadable. Ointments are very good at helping the skin retain moisture but they are often disliked because of their greasiness.

**CREAMS** are thick mixtures of greases in water or another liquid. They contain a lower proportion of grease than ointments, making them less greasy. A warning: creams often contain stabilizers and preservatives to prevent separation of their main ingredients, and these additives can cause skin irritation or even allergic reactions for some people.

**LOTIONS** are mixtures of oil and water, with water being the main ingredient. Most lotions do not function well as moisturizers for people with dry skin conditions because the water in the lotion evaporates quickly.

# WHAT MOISTURIZER SHOULD I USE?

The importance of moisturizing cannot be over emphasized as a treatment for eczema and sensitive skin. Moisturizers maintain skin hydration and barrier function. Generic petroleum jelly and mineral oil (without additives) are two of the safest, most effective moisturizing products.

Following are a few suggestions:

- Albolene Moisturizing Cleanser®
- · Aquaphor® Healing Ointment
- AVEENO® Eczema Therapy Moisturizing Cream
- CeraVe<sup>™</sup> Moisturizing Lotion or Cream
- Cetaphil® Moisturizing Cream
- Cetaphil® Restoraderm® Moisturizer
- Crisco Regular Shortening
- Curél Itch Defense Skin Balancing Moisture Lotion
- Eucerin® Calming Creme or Original Cream
- Exederm® Intensive Moisture Cream
- Hydrolatum®
- La Roche-Posay® Lipikar Balm
- MD Moms® Baby Silk Daily Skin Protection Moisturizing Balm
- Moisturel® Therapeutic Cream
- Mustela® Stelatopia Moisturizing Cream
- Theraplex® Emollient or Lotion
- Triple Cream®
- Vanicream<sup>™</sup> Moisturizing Skin Cream
- Vaseline® Petroleum Jelly

Apply moisturizer to your skin immediately after your bath or shower and throughout the day whenever your skin feels dry or itchy. Some people prefer to use creams and lotions during the day and ointments and creams at night. If you can't find the product you want, ask a pharmacist to order it for you in the largest container available. Buying your moisturizers in large containers like one-pound jars may save you a great deal of money.

# WHAT ARE PROPER MOISTURIZING TECHNIQUES?

- Just as it is important to use proper bathing techniques, it is important to properly apply moisturizers to your skin within three minutes of showering or bathing.
- While your skin is still wet, apply prescription medications, and then apply a moisturizer to all your skin.

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- A thick bland product is best.
- Dispense the moisturizer from large jars with a clean spoon, butter knife, or pump to avoid contamination.
- Take a dollop of moisturizer from the jar, soften it by rubbing it between your hands, and apply it using the palm of your hand stroking in a downward direction.
- Do NOT rub by stroking up and down or around in circles.
- Leave a tacky film of moisturizer on your skin; it will be absorbed in a few minutes.

Everyone has different preferences concerning how products feel on their skin, so try different products until you find one that feels comfortable. Continue use of the moisturizer(s) even after the affected area heals to prevent recurrence.

# **HOW CAN I REDUCE SKIN IRRITATION?**



After bathing and moisturizing, the next important step is to attempt to reduce skin irritation.

**DON'T SCRATCH OR RUB THE SKIN.** These actions can worsen any itch. Instead, apply a moisturizer whenever the skin feels dry or itchy. A cool gel pack can provide some relief from itch.

**WASH ALL NEW CLOTHES BEFORE WEARING THEM.** This removes formaldehyde and other potentially irritating chemicals which are used during production and packing.

ADD A SECOND RINSE CYCLE TO ENSURE THE REMOVAL OF SOAP IF YOU ARE CONCERNED. Use a mild detergent that is dye-free and fragrance-free.

WEAR GARMENTS THAT ALLOW AIR TO PASS FREELY TO YOUR SKIN. Open-weave, loose-fitting,

cotton-blend clothing may be most comfortable. Avoid wearing wool.

WET WRAP THERAPY CAN EFFECTIVELY REHYDRATE AND CALM THE SKIN. Soak in a bath, and then apply moisturizer. Medication should also be applied if currently prescribed. The bandages, moistened in warm water until they are slightly damp, are then wrapped around the area. Dry bandages are wrapped over the wet bandages. In place of bandages, athletic socks, or moistened pajamas worn underneath a set of dry pajamas can be used with children and infants.

WORK AND SLEEP IN COMFORTABLE SURROUNDINGS with a fairly constant temperature and humidity level. Cooler temperatures are preferred but not so cool as to initiate chilling.

KEEP FINGERNAILS VERY SHORT AND SMOOTH by filing them daily to help prevent damage due to scratching.

MAKE APPROPRIATE USE OF SEDATING ANTIHISTAMINES, which may reduce itching to some degree through their tranquilizing and sedative effects.

**USE SUNSCREEN ON A REGULAR BASIS AND ALWAYS AVOID GETTING SUNBURNED.** Use a sunscreen with an SPF of 15 or higher. Sunscreens made for the face are often less irritating than regular sunscreens. Zinc oxide or titanium dioxide—based products are less irritating.

**GO FOR A SWIM**, which can provide good hydration. Chlorine can also decrease bacteria on the skin that can cause itching or develop into an infection. Of course, residual chlorine or bromine left on the skin after swimming in a pool or hot tub may be irritating, so take a quick shower or bath immediately after swimming, washing with a mild cleanser from head to toe, and then apply an appropriate moisturizer while still wet.

For a complimentary copy of the NEA print newsletter, *The Advocate*, and an eczema information package, please contact us. We are always here to help!

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JOIN NEA's ONLINE SUPPORT COMMUNITY: community.nationaleczema.org

This information sets forth current opinions from recognized authorities, but it does not dictate an exclusive treatment course. Persons with questions about a medical condition should consult a physician who is knowledgeable about that condition.

The National Eczema Association (NEA) improves the health and quality of life for individuals with eczema through research, support, and education. NEA is entirely supported through individual and corporate contributions and is a 501(c)(3) tax-exempt organization. NEA is the only organization in the United States advocating solely for eczema patients.

Acknowledgments: The National Eczema Association (NEA) acknowledges Anna L. Bruckner, MD, Sarah Chamlin, MD, and Sandra Oehlke, CPNP, for their editorial contributions to this brochure.

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Learn more about: Bathing Moisturizing Skin Care Treatment

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# **Exhibit G – Jackson Declaration**

(Screen Shot of the website http://www.nationaleczema.org/seal-acceptance/product-directory-personal-care)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514





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Seal of Acceptance

Home » Seal of Acceptance » Product Directory

# SEAL OF ACCEPTANCE: PRODUCT DIRECTORY - PERSONAL CARE



The products listed have applied for and been awarded the National Eczema Association Seal of Acceptance. Select particular product for more information, or scroll down the page to view all products. Read information about the Seal of Acceptance criteria and application process here.

The importance of moisturizing cannot be over emphasized as a treatment for eczema and sensitive skin. Moisturizers maintain skin hydration and barrier function. Generic petroleum jelly and mineral oil (without additives) are two of the safest, most effective moisturizing

Special Note: Nut oil, food/plant derivatives, and some natural ingredients can raise allergy issues for some individuals, and be of concern for pediatric patients. Each Seal of Acceptance Review will alert consumers to the presence of nut oils and similar natural ingredients. Contact your medical professional for guidance.

- AVEENO® Baby Eczema Therapy Moisturizing Cream
- AVEENO® Baby Cleansing Therapy Moisturizing Wash
- AVEENO® Eczema Therapy Moisturizing Cream
- Albolene Moisturizing Cleanser®
- · Bella Dry Skin Formula Moisturizing Body Bar
- Ceratopic® Ceramide Replenishing Cream
- CeraVe® Hydrating Cleanser
- CeraVe® Moisturizing Cream
- CeraVe® Moisturizing Lotion
- Cetaphil® RESTORADERM® Body Wash
- Cetaphil® RESTORADERM® Moisturizer
- · Curél Itch Defense Ski
- Balancing Moisture Lotion
- Exederm Body Lotion
- Exederm Body Oil
- Exederm Cleansing Wash
- Exederm Flare Control Cream
- Exederm Intensive Moisture Cream
- Exederm Baby Bath
- Exederm Baby Lotion
- Exederm Baby Moisturizing Cream
- Exederm Baby Oil
- Exederm Baby Shampoo
- Exederm Conditioner
- Exederm Shampoo

- Hydrolatum®
- Kiss of Nature Oh My Baby!! Liquid Castile Hand & Body Soap
- Kiss of Nature Oh My Baby!! Moisturizing Castile Body Bar
- Kiss of Nature Oh My Sassy Baby!!
- MD Moms® Baby Silk Gentle All-Over Clean Hair & Body Wash
- MD Moms® Baby Silk Gentle All-Over Clean Hair & Body Wash unfragranced
- MD Moms® Baby Silk Daily Skin Protection Moisturizing Balm
- MD Moms® Baby Silk Daily Skin Protection Moisturizing Balm unfragranced
- · Moisturizing Castile Bar with Goat Milk
- Mustela® Dermo-Pediatrics Stelatopia Cream Cleanser
- Mustela® Dermo-Pediatrics Stelatopia Milky Bath Oil
- Mustela® Dermo-Pediatrics Stelatopia Moisturizing Cream
- Neosporin® Eczema Essentials™
- Skin Free® Extra Moisturizing Soap
- Theraplex Clear Lotion
- Theraplex Emollient
- Triple Cream®

**AVEENO® BABY ECZEMA THERAPY MOISTURIZING CREAM** 

**AVEENO® BABY CLEANSING THERAPY MOISTURIZING WASH** 

**AVEENO® ECZEMA THERAPY MOISTURIZING CREAM** 

www.aveeno.com

The moisturizing creams are especially formulated to be mild even for itchy, extra dry skin. The creamy baby cleansing wash is formulated to gently cleanse without damaging the skin's barrier and is clinically mild for sensitive skin.



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SPECIAL EVENTS





Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

The AVEENO® Baby Eczema Therapy Moisturizing Cream and AVEENO® Eczema The Flour, Oat Oil and Oat Extract. These ingredients may be of concern as it relates to futu.

The AVEENO® Baby Cleansing Therapy Moisturizing Wash contains methylisothiazolin are potential irritants at concentration levels thought to be insignificant for most patients (Oat Flour (Avena Sativa)). This ingredient may be of concern as it relates to future pote Information regarding the FDA classification of colloidal oat can be found at: Federal Dr

# **ALBOLENE MOISTURIZING CLEANSER®**

### www.albolenecleanser.com

Albolene® Moisturizing Cleanser is an effective and gentle makeup remover that also provides great moisturizing benefits. Albolene contains mineral oil, petrolatum paraffin, ceresin and beta-carotene. Used immediately after the bath or shower, Albolene is a good occlusive preparation to seal in the water and hydrate the skin.



www.albolenecleanser.com

### Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin.

# **BELLA DRY SKIN FORMULA MOISTURIZING BODY BAR**

# www.buybellasoap.com

Bella Dry Skin Formula™ uses ingredients with quick skin penetration that act as humectants, attracting external moisture, holding moisture close to the skin, and forming a breathable film to prevent moisture loss. Fragrance-free and no preservatives or dyes.



www.buybellasoap.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product contains ingredients that may be of concern as it relates to food allergies and skin sensitization. Bella Dry Skin Formula Moisturizing Body Bar contains coconut oil (20 – 25%) goat milk (5 – 15%) and shea butter (1 – 5%)

# SKINMEDICA, INC. **CERATOPIC® CERAMIDE REPLENISHING CREAM**

# www.desonate.com

Ceratopic Ceramide Replenishing Cream relieves dryness, itching, and irritation for a noticeably smoother, silkier feel as it restores the skin's natural barrier function to provide long-lasting hydration.



www.desonate.com

# ARTICLES/RESEARCH

**Vaccination** 

Recommendations for People with Egg Allergy

**Education Resource Center:** What Causes Eczema

**Education Resource Center:** Guide to Ingredients to Avoid

Are Allergies to Blame?

# ASK THE DOCTOR/EXPERTS

Good News for Kids with **Food Allergies** 

**Dyshidrotic Eczema?** 

Eyelid Eczema?

Food Allergy Guidelines as They Relate to Eczema

Eczema and Long-term **Allergies Linked** 

> 1 2 next > last »

# SCRATCH PAD

Corn Allergy Triggers

Mathylisothiazolinone - in Shampoo - Allergy

Milk Allergies

Adult Eczema - Pollen & Dust Mites Allergy

Aveeno and Cotton Dacron **Blends** 

> 3 next >

# OTHER

Seal of Acceptance: Product **Directory - Fabrics** 

Seal of Acceptance: Product Directory - Household **Products** 

Video: Atopic Dermatitis, Food Allergies, and National Guidelines Often Go Hand in Hand

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### Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product may contain potential irritants at concentration levels thought to be insignificant for most patients. Manufacturer has provided extensive testing and sensitivity data to determine acceptability. These ingredients include methylparaben and propylparaben. This product contains Avena Sativa (Oat) Kernel Extract. This ingredient may be of concern as it relates to future potential food allergies.

### **CERAVE® HYDRATING CLEANSER**

### **CERAVE® MOISTURIZING CREAM**

### **CERAVE® MOISTURIZING LOTION**

### www.cerave.com

CeraVe® Moisturizing Cream and CeraVe® Moisturizing Lotion increases the skin's ability to attract, hold and distribute moisture and also form a protective layer over the skin's surface to help prevent moisture loss. CeraVe® Hydrating Cleanser gently cleanses the skin while helping to maintain the right moisture balance. These products are fragrance-free, non-irritating and non-comedogenic.



www.cerave.com

### Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

These products may contain potential irritants at concentration levels thought to be insignificant for most patients. Manufacturer has provided extensive testing and sensitivity data to determine acceptability. These ingredients include the preservatives methylparaben and propylparaben.

### **CETAPHIL® RESTORADERM® BODY WASH**

### **CETAPHIL® RESTORADERM® MOISTURIZER**

### www.cetaphil.com

RESTORADERM® Body Wash and Moisturizer soothe, restore and moisturize to help alleviate the dryness and itching associated with eczema and atopic dermatitis. RESTORADERM® products are fragrance free and clinically proven to be non-irritating and non-drying to the skin of people with atopic dermatitis and eczema.



www.cetaphil.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

These products may contain known allergens that may cause reactions for some food allergic patients. These products contain butyrospermum Parkii (shea butter) and Helianthus Annuus (sunflower seed oil). These are rare allergens, and may be of concern as it relates to food allergies. Galderma Laboratories states that the manufacturer of the sunflower seed oil certifies that the oil is refined. Since the allergenic moieties are thought to be in the protein, NEA notes the absence of such in the component used for the Cetaphil® RESTORADERM® Moisturizer.

# **CURÉL ITCH DEFENSE SKIN BALANCING MOISTURE LOTION**

# www.curel.com

This fragrance-free formula brings long-lasting itch relief to your skin everyday by instantly rebalancing dry, aggravated skin while also controlling flare-ups. In addition it is dermatologist, pediatrician and allergist tested.



www.curel.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product may contain potential irritants at concentration levels thought to be insignificant for most patients. Manufacturer has provided extensive testing and sensitivity data to determine acceptability. These ingredients include methylparaben, propylparaben, and propylene glycol isosterate.

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**EXEDERM BODY LOTION** 

**EXEDERM BODY OIL** 

**EXEDERM CLEANSING WASH** 

**EXEDERM FLARE CONTROL CREAM** 

**EXEDERM INTENSIVE MOISTURE CREAM** 

**EXEDERM BABY BATH** 

**EXEDERM BABY LOTION** 

**EXEDERM BABY MOISTURIZING CREAM** 

**EXEDERM BABY OIL** 

**EXEDERM BABY SHAMPOO** 

**EXEDERM CONDITIONER** 

**EXEDERM SHAMPOO** 

www.exederm.com

The Exederm products have been formulated to avoid harsh chemicals and unnecessary additives that may irritate and cause a rash on sensitive skin or trigger an eczema flare-up.

# **Exederm Skin Care Range:**

- Body Lotion
- Body Oil
- Cleansing Wash
- Flare Control Cream
- Intensive Moisture Cream

# exederm skin care range



www.exederm.com

# Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin.

# **Exederm Baby Care Range:**

- Baby Bath
- Baby Lotion
- Baby Moisturizing Cream
- Baby Oil
- Baby Shampoo

exederm children's range



www.exederm.com

# Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin.

# **Exederm Hair Care Range:**

- Conditioner
- Shampoo

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www.exederm.com

Seal of Acceptance Rating: Shampoo 5 out of 5 \* \* \* \* \* Seal of Acceptance Rating: Conditioner 4 out of 5 \*\*\*\*

contains plant derived dimethylstearmine - no testing data available

# **HYDROLATUM®**

# www.hydrolatum.com

Hydrolatum® provides serious relief for seriously dry skin. Hydrolatum's soothing formulate creates a protective barrier on the skin's surface, locking in moisture and locking out irritants. Apply sparingly to affected areas, as often as needed. Ideal for sensitive skin!



www.hydrolatum.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

Product may contain a potential irritant at concentration levels thought to be insignificant for most patients. Manufacturer has provided extensive testing and sensitivity data to determine acceptability. This ingredient is methylparaben.

# KISS OF NATURE OH MY BABY!! LIQUID CASTILE HAND & BODY SOAP

KISS OF NATURE OH MY BABY!! MOISTURIZING CASTILE BODY BAR

# KISS OF NATURE OH MY SASSY BABY!! MOISTURIZING CASTILE BAR WITH GOAT MILK

# www.kissofnaturesoap.com

Fresh, long-lasting handcrafted soap good for your skin! Kiss of Nature natural soaps are animal-free and crafted from the highest quality plant oils without damaging or harsh detergents. Three Kiss of Nature Products have received the Seal of Acceptance:

# KISS OF NATURE



www.kissofnaturesoap.com

# Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin. Oh My Baby! Kiss of Nature Fragrance Free Moisturizing Body Bar

Oh My Baby! Kiss of Nature Fragrance Free Liquid Castile Hand Soap

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product contains an ingredient that may be of concern as it relates to food allergies and skin sensitization. Oh My Sassy Baby! Kiss of Nature Handcrafted Soap - Fragrance-Free Moisturizing Body Bar with Goat Milk contains 25% Fresh Raw Goat Milk.

Oh My Sassy Baby! Kiss of Nature Fragrance Free Moisturizing Body Bar with Goat Milk

MD MOMS® BABY SILK GENTLE ALL-OVER CLEAN HAIR & BODY WASH

MD MOMS® BABY SILK GENTLE ALL-OVER CLEAN HAIR & BODY WASH - UNFRAGRANCED

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### MD MOMS® BABY SILK DAILY SKIN PROTECTION MOISTURIZING BALM

### MD MOMS® BABY SILK DAILY SKIN PROTECTION MOISTURIZING BALM - UNFRAGRANCED

### www.mdmoms.com

The hair & body wash includes a blend of gentle ingredients that won't interfere with the skin's natural moisture barrier. The moisturizing balm is quick-absorbing, lightweight, and is perfect for restoring and maintaining the skin's moisture barrier. These products are paraben-free, preservative-free, sulfate-free, hypoallergenic and contain no phthalates, lanolin, mineral oil, petroleum, waxes, wheat or gluten.



www.mdmoms.com

### EASE Rating: 4 out of 5 \* \* \* \*

The MD Moms® Baby Silk Gentle All-Over Clean Hair & Body Wash and MD Moms® Baby Silk Daily Skin Protection Moisturizing Balm products contain fragrance at concentration levels thought to be insignificant for most patients. The manufacturer has provided extensive information that the fragrance blend meets current standards to be free from known sensitizing agents.

Further information regarding these products' fragrance can be found here.

The MD Moms® Baby Silk Daily Skin Protection Moisturizing Balm (both the regular and the unfragranced versions) contain butyrospermum parkii (shea butter), a rare allergen that may be of concern as it relates to food allergies.

### **MUSTELA® DERMO-PEDIATRICS STELATOPIA CREAM CLEANSER**

MUSTELA® DERMO-PEDIATRICS STELATOPIA MILKY BATH OIL

# **MUSTELA® DERMO-PEDIATRICS STELATOPIA MOISTURIZING CREAM**

### www.mustelausa.com

Mustela® Dermo-Pediatrics Stelatopia Cream Cleanser, Stelatopia Milky Bath Oil, and Stelatopia Moisturizing Cream are designed to address the needs of sensitive skin. These products are hypoallergenic, non-irritating, fragrance-free, paraben-free and have no artificial colorants.



www.mustelausa.com

# Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin.

# **NEOSPORIN®**

# www.neosporinessentials.com

The NEOSPORIN® ESSENTIALS™ products have RELIPID™ formulas that contain a blend of ingredients to help retain moisture for healthy-looking skin.



www.neosporinessentials.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

The Neosporin® Moisture Essentials™ Daily Body Wash contains sodium laureth sulfate and dipropylene glycol. These ingredients are potential irritants at concentration levels thought to be insignificant for most patients.

The Neosporin® Eczema Essentials™ Daily Moisturizing Cream contains colloidal oatmeal, oat kernel oil and oat kernel extract, and the Neosporin® Moisture Essentials™ Daily Body Wash contains oat kernel extract. These ingredients may be of concern as it relates to future potential food allergies.

Information regarding the FDA classification of colloidal oat can be found at: Federal Drug Administration Colloidal Oatmeal Classification.

# **SKIN FREE ® EXTRA MOISTURIZING SOAP**

### www.skinfree.net

Skin Free Extra Moisturizing Soap is extra moisturizing for delicate, sensitive or very dry skin. The soap bar may

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also be used as a perfect conditioning shampoo with no greasy look after.



www.skinfree.net

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product may contain potential irritants at concentration levels thought to be insignificant for most patients. This product may also contain known allergens that may cause reactions for some food allergic patients.

Skin Free® Extra Moisturizing Soap contains Sodium Hydroxide 11% identified by the Environmental Working Group's SKIN DEEP cosmetic safety database as a moderate hazard at low doses. This product contains shea butter and coconut oil, which may be of concern as it relates to potential food allergies, but is thought to be unlikely; no testing data exists.

### THERAPLEX CLEAR LOTION

# THERAPLEX EMOLLIENT

www.theraplex.com

Theraplex Clear Lotion and Theraplex Emollient repair the barrier layer and immediately enables the skin to retain moisture and heal itself. The special petrolatum fraction forms a greaseless, durable micro-protective barrier.



www.theraplex.com

# Seal of Acceptance Rating: 5 out of 5 \* \* \* \* \*

These products do not contain known irritants to eczema or sensitive skin.

# TRIPLE CREAM® BY SUMMERS LABORATORIES, INC.

# www.triple-cream.com

New from the makers of Triple Paste, Triple Cream Eczema Care is a premium formula for baby's severe dry skin. The fragrance free formula provides soothing relief for baby eczema.



www.triple-cream.com

# Seal of Acceptance Rating: 4 out of 5 \* \* \* \*

This product may contain potential irritants at concentration levels thought to be insignificant for most patients.

Triple Cream® contains benzyl alcohol identified by the Environmental Working Group's SKIN DEEP cosmetic safety database as a moderate hazard at low doses and sorbitan sesquioleate identified as a low hazard in moderate doses. This product also contains oat (avena sativa) extract, which may be of concern as it relates to potential food allergies, but is thought to be unlikely; no testing data exists.

### Rate this item:

Average: 3.9 (7 votes)

Learn more about: Allergies Bathing Ingredients Irritants-Allergens Moisturizing Products Seal of Acceptance Treatment

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# Exhibit H – Jackson Declaration

(Registrant's Response to Petitioner Sköld's First Set of Interrogatories and Requests for Production of Documents and Things)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld

Petitioner,

v.

Cancellation No.: 92052897

Mark: RESTORADERM

Galderma Laboratories, Inc.

Registrant.

Reg. Nos.: 2,985,751 and 3,394,514

REGISTRANT'S RESPONSE TO PETITIONER SKÖLD'S FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODCTION OF DOCUMENTS AND THINGS

Pursuant to the provisions of: (a) 37 C.F.R. §§ 2.116(a) and 2.120, Rule 33 of the Federal Rules of Civil Procedure, TBMP §§ 403.02 and 408.01; (b) and 37 C.F.R. §§ 2.120, Rule 34 of the Federal Rules of Civil Procedure and TBMP §§ 403.03 and 408.01, Galderma Laboratories, Inc. ("Registrant") herewith responds to Thomas Sköld's ("Petitioner") First Set of Interrogatories ("Interrogatory or Interrogatories") and Requests for Production of Documents and Things ("Request" or "Requests") as follows:

# PRELIMINARY STATEMENT

On April 27, 2012, Registrant filed with the Board, and served upon Petitioner, a Motion for Partial Summary Judgment ("Motion") on Petitioner's cause for abandonment. Registrant expects that the Board will soon suspend the current proceedings during the pendency of such Motion. Registrant further notes that the disposition of the Motion will significantly affect the relevance of many of Petitioner's Interrogatories and Requests. Accordingly, Registrant herein provides responses to Petitioner's Interrogatories and Requests to the extent necessary to preserve Registrant's rights and intends to provide substantive responses and produce responsive documents after the proceedings are resumed, following the Board's disposition of the Motion.

# **GENERAL OBJECTIONS**

- 1. Registrant objects to Petitioner's Interrogatories and Requests to the extent that they seek to impose obligations beyond those imposed by Rule 26 of the Federal Rules of Civil Procedure. In particular, Rule 26(b) limits the scope of discovery to "any matter, not privileged, which is relevant to the subject matter involved in the pending action."
- 2. Registrant objects to any specific Interrogatory or Request to the extent that it seeks information subject to (i) the attorney-client privilege, (ii) the attorney work product doctrine, (iii) the protection afforded consulting experts pursuant to Federal Rule of Civil Procedure 26(b)(4)(B), (iv) the self-critical analysis privilege, (v) the investigative privilege, (vi) the party communications privilege, (vii) the witness statement privilege, or (viii) any other privilege or protection afforded by state or federal law. To the extent that an Interrogatory or Request can be construed as seeking information subject to such privileges, or any other privilege afforded by law, Registrant hereby claims such privilege and/or invokes the attorney work product doctrine.
- 3. Registrant objects to any specific Interrogatory or Request to the extent it calls for information that is publicly available to Petitioner because such Interrogatory or Request is unduly burdensome, oppressive, and annoying since Petitioner has access to such information.
- 4. Registrant objects to the extent the Interrogatories and Requests seek information other than that which may be obtained through a reasonably diligent search of its records.
- 5. Registrant objects to each Interrogatory or Request to the extent that it seeks information not within Respondent's possession, custody, or control.
- 6. Registrant objects to the use of "all," "each," and the like in Petitioner's Interrogatories and Requests, to the extent same renders the Interrogatories and Requests overly broad and unduly burdensome. Unless otherwise indicated by objection, Registrant will provide information and documents that Registrant was able to locate as a result of a comprehensive search of Registrant's business records. However, where the

scope of information requested is unduly burdensome, Registrant will respond by representative information

only, as sanctioned by the Board. To the extent that Registrant produces any such document, it does not

concede that the document produced is relevant to this action. Respondent produces the documents without

waiving or intending to waive any objection to competency, relevancy, or admissibility as evidence of any

matter referred to or made the subject of any answer provided, including at the trial of this action.

Registrant objects to the Petitioner's definition of "identify," when used in reference to a

natural individual, as including the individual's home address, on grounds that such information is not

reasonably calculated to lead to the discovery of admissible evidence. Where Registrant has identified, and

where it will identify, an individual, Registrant will provide that individual's business address only, if the

individual has a known business address.

7.

8. Registrant objects to Petitioner's definition of "identify" and "identification" when used with

respect to a document for which Registrant claims privilege as overly broad, unduly burdensome, oppressive,

not reasonably calculated to lead to the discovery of admissible evidence, and harassing.

9. Registrant expressly reserves the right to amend, supplement, or change its responses to

Petitioner's Interrogatories and Requests with information learned in the course of further investigation and

discovery.

10. The objections listed above are not intended to be exhaustive. Registrant objects to each of

the prefatory statements, definitions, and instructions, and Petitioner's Interrogatories and Requests to the

extent that they purport to impose obligations upon Registrant that exceed those required by the Federal Rules

of Civil Procedure, the Federal Rules of Evidence, Title 37 of the Code of Federal Regulations, any order of

the Trademark Trial and Appeal Board, or any other applicable law.

Registrant incorporates by reference to each and every Response to Petitioner's Interrogatories and

Requests herein, the General Objections set forth above.

# **RESPONSES TO INTERROGATORIES**

**Interrogatory No. 1:** 

Identify all documents upon which Registrant intends to rely in this proceeding.

Response:

Registrant objects to this Interrogatory under T.B.M.P. § 414(7) on the ground that a party is not obligated to specify the evidence or documents it intends to present in advance of trial. Registrant further objects to this Interrogatory on the ground that complete compliance with "all documents" is unduly burdensome.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 2:** 

Identify each person whom Registrant may call to testify on his behalf in this proceeding.

Response:

Registrant objects to this Interrogatory under T.B.M.P. § 414(7) on the ground that a party is not obligated to identify witnesses it may call to testify on its behalf.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 3:** 

Identify all persons having knowledge of the allegations and facts that you assert in response to these interrogatories, and describe the substance of those persons' knowledge.

Response:

Registrant objects to this Interrogatory on the ground that complete compliance with "all persons" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 4:** 

Describe in detail how the term "Restoraderm" was first conceived of.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 5:** 

Describe each product that has been marketed under the mark "Restoraderm".

Response:

Subject to and without waiving the general objections, Registrant shall provide an appropriate response

as described in the Preliminary Statement.

**Interrogatory No. 6:** 

State the date of, and describe in detail the circumstances of, Registrant's first use of the mark

"Restoraderm" in commerce in connection with the sale, offering for sale, distribution, or advertising of a

dermatology product.

Response:

Subject to and without waiving the general objections, Registrant shall provide an appropriate response

as described in the Preliminary Statement.

**Interrogatory No. 7:** 

State the date of, and describe in detail the circumstances of, Registrant's first use of the mark

"Cetaphil Restoraderm" in commerce in connection with the sale, offering for sale, distribution, or advertising

of a dermatology product.

Response:

Subject to and without waiving the general objections, Registrant shall provide an appropriate response

as described in the Preliminary Statement.

**Interrogatory No. 8:** 

Describe in detail all facts and identify all documents and things showing that the mark Restoraderm

was irrevocably assigned in either the 2002 or 2004 Agreement, which facts, document or things are in

addition to the 2002 Agreement and the 2004 Agreement themselves.

Response:

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and . . .

all documents and things" is overly broad and unduly burdensome. Registrant further objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence. Moreover, Registrant objects to the extent that the Interrogatory calls for a

legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

Interrogatory No. 9:

Describe in detail all facts and identify all documents and things showing that the mark Restoraderm

was assigned in either the 2002 Agreement or the 2004 Agreement, without contingency that the full measure

of contemplated consideration being paid, which facts, document or things are in addition to the 2002

Agreement and the 2004 Agreement themselves.

**Response:** 

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and ...

all documents and things" is overly broad and unduly burdensome. Registrant further objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal

conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 10:** 

Identify the chief officer of Registrant in charge of making applications to the U.S. Food and Drug

Administration seeking regulatory approval for drug compositions, therapeutic compositions, or the like (the

"FDA Compliance Officer").

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

**Interrogatory No. 11:** 

Describe in detail the basis, if any, by which the FDA Compliance Officer believes that each given

product sold under the mark "Cetaphil Restoraderm" in the United States during 2011 or earlier is a

"therapeutic skin care preparation" and/or provides a "treatment of skin disorders."

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the

extent that the Interrogatory calls for a legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 12:** 

Describe in detail the basis, if any, by which the FDA Compliance Officer believes that each given

product sold under the mark "Cetaphil Restoraderm" in the United States during 2011 or earlier is sold as a

"therapeutic skin care preparation" and/or sold to provide a "treatment of skin disorders."

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the

extent that the Interrogatory calls for a legal conclusion. Registrant further objects that this Interrogatory is

duplicative of Interrogatory No. 11 and it is therefore harassing.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

# **Interrogatory No. 13:**

Describe in detail the basis by which the FDA Compliance Officer believes that given each product sold under the mark "Cetaphil Restoraderm" in the United States during 2012 is a "therapeutic skin care preparation" and/or provides a "treatment of skin disorders."

# Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Interrogatory calls for a legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 14:**

Describe in detail the basis by which the FDA Compliance Officer believes that each given product sold under the mark "Restoraderm" or "Cetaphil Restoraderm" in the United States during 2012 is sold as a "therapeutic skin care preparation" and/or sold to provide a "treatment of skin disorders."

# Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Interrogatory calls for a legal conclusion. Registrant further objects that this Interrogatory is duplicative of Interrogatory No. 13 and it is therefore harassing.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 15:** 

Identify the chief officer of Registrant in charge of making marketing the product sold under the mark

"Cetaphil Restoraderm" (the "Marketing Officer").

**Response:** 

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 16:** 

Describe in detail the basis by which the Marketing Officer believes that each given product sold under

the mark "Restoraderm" or "Cetaphil Restoraderm" in the United States during 2011 or earlier is a "therapeutic

skin care preparation" and/or provides a "treatment of skin disorders."

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the

extent that the Interrogatory calls for a legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

**Interrogatory No. 17:** 

Describe in detail the basis by which the Marketing Officer believes that each given product sold

under the mark "Restoraderm" or "Cetaphil Restoraderm" in the United States during 2011 or earlier is sold as

a "therapeutic skin care preparation" and/or sold to provide a "treatment of skin disorders."

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the

extent that the Interrogatory calls for a legal conclusion. Registrant further objects that this Interrogatory is

duplicative of Interrogatory No. 16 and it is therefore harassing.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 18:** 

Describe in detail the basis by which the Marketing Officer believes that each given product sold under

the mark "Restoraderm" or "Cetaphil Restoraderm" in the United States during 2012 is a "therapeutic skin care

preparation" and/or provides a "treatment of skin disorders." Moreover, Registrant objects to the extent that

the Interrogatory calls for a legal conclusion.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor

reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

**Interrogatory No. 19:** 

Describe in detail the basis by which the Marketing Officer believes that each given product sold under

the mark "Restoraderm" or "Cetaphil Restoraderm" in the United States during 2012 is sold as a "therapeutic

skin care preparation" and/or sold to provide a "treatment of skin disorders."

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects that this Interrogatory

is duplicative of Interrogatory No. 18 and it is therefore harassing. Registrant further objects to the extent that

the Interrogatory calls for a legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 20:** 

Describe all facts and identify all documents and things relating to and showing Registrant's design or

implementation of studies intended to support a New Drug Application under the U.S. Food and Drug Act, or

to support a comparable regulatory approval (including without limitation DESI pending, OTC Monograph, or

GRASE), for the marketing of any product sold in the U.S. in 2011 under the mark "Restoraderm" or

"Cetaphil Restoraderm" for treatment of Eczema.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all

documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 21:** 

Describe all facts and identify all documents and things relating to and showing Registrant's design or

implementation of studies initiated on or after January 1, 2007 intended to support a New Drug Application

under the U.S. Food and Drug Act, or to support a comparable regulatory approval (including without

limitation DESI pending, OTC Monograph, or GRASE), for the marketing of a product intended to be, or later

elected to be, sold under the mark "Restoraderm" for "Cetaphil Restoraderm" or treatment of Eczema.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all

documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 22:** 

Describe all facts and identify all documents and things relating to and showing Registrant's design or

implementation of studies initiated on or after January 1, 2007 intended to support a New Drug Application

under the U.S. Food and Drug Act, or to support a comparable regulatory approval (including without

limitation DESI pending, OTC Monograph, or GRASE), for the marketing of a product intended to be, or later

elected to be, sold under the mark "Restoraderm" or "Cetaphil Restoraderm" for treatment of a skin disorder.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 23:** 

Describe all facts and identify all documents and things relating to Registrant's decision to file for the application that matured to U.S. Reg. No. 3394514.

**Response:** 

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 24:** 

Describe all products that are being sold in the United States, or in development for sale in the United States, under U.S. Reg. No. 2885751.

Response:

Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 25:**

Describe all products that are being sold in the United States, or in development for sale in the United States, under U.S. Reg. No. 3394514.

# Response:

Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 26:**

Describe all facts and identify all documents and things relating to Galderma's decision that it could retain the Restoraderm trademark it nominally acquired from Collagenex.

# Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to this Interrogatory to the extent that it is premised upon certain factual and legal conclusions that are at issue in this Cancellation.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement

# **Interrogatory No. 27:**

Describe all facts and identify all documents and things relating to Galderma's decision to relinquish the patent estate assigned to Sköld by the Assignment of Patents dated February 22, 2010 and the product identified for return to Sköld in the

# Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 28:**

In Petitioner's Response to Registrant's First Set of Interrogatories, Petitioner lays out his calculation of having received dollars from Collagenex. Please describe in detail any further payments from Collagenex to Sköld not identified in Petitioner's Response to Registrant's First Set of Interrogatories.

#### Response:

Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 29:** 

Describe all facts and identify all documents and things relating to any efforts by Galderma to seek a

partnership, collaboration, joint venture or the like with another pharmaceutical company (excluding

Collagenex) that would use, or later elect to use, the mark Restoraderm.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and

things" is overly broad and unduly burdensome. Registrant further objects to the extent this Interrogatory

seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of

admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement

**Interrogatory No. 30:** 

Describe all facts and identify all documents and things relating to any inquiries to Galderma from

third parties, including consumers, indicating or suggesting confusion between Registrant's Mark and the

technology and compositions that Petitioner terms RESTORADERM Technology or the these third parties

associate with Petitioner.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all

documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 31:** 

Describe all facts and identify all documents and things relating to any inquiries to Galderma from

third parties, including consumers, inquiring as to whether items marketed under the mark "Restoraderm" or

"Cetaphil Restoraderm" are affiliated in any way with Petitioner.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all

documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this

Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

**Interrogatory No. 32:** 

Describe in detail all facts and identify all documents and things showing commercial or development

activity by Registrant on RESTORADERM Technology that occurred on or after June 1, 2007.

Response:

Registrant objects to this Interrogatory on the grounds that it is vague and ambiguous. Registrant

further objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all

documents and things" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 33:**

Describe in detail all facts and identify all documents and things relating to Registrant's decision to use the mark "**DERMACONTROL**".

# Response:

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome. Registrant further objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

## **Interrogatory No. 34:**

Describe in detail all facts and identify all documents and things relating to any decision by Registrant to use the mark "**DERMACONTROL**" in place of "Restoraderm".

## Response:

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and ... all documents and things" is overly broad and unduly burdensome. Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# **Interrogatory No. 34:** [sic]

Describe in detail all facts and identify all documents and things relating to any decision by Registrant to discontinue, in the short term or the long term, the mark "Restoraderm".

# Response:

Registrant objects to this Interrogatory on the ground that complete compliance with "all facts and . . . all documents and things" is overly broad and unduly burdensome. Registrant objects to the extent this Interrogatory seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall provide an appropriate response as described in the Preliminary Statement.

# RESPONSES TO REQUESTS FOR PRODUCTION

# **Request for Production No. 1:**

All documents and things identified in Registrant's Initial Disclosures served in connection with this Cancellation not already produced.

# Response:

Subject to and without waiving the general objections, Registrant shall produce appropriate documents as described in the Preliminary Statement.

## **Request for Production No. 2:**

All documents and things not identified in Registrant's Initial Disclosures served in connection with this Cancellation, which nonetheless were reviewed or relied upon in preparing Registrant's Initial Disclosures.

#### Response:

Subject to and without waiving the foregoing objections and the general objections, Registrant shall produce appropriate documents as described in the Preliminary Statement.

# **Request for Production No. 3:**

All documents and things identified in Registrant's responses to Petitioner's First Set of Interrogatories set forth above.

# Response:

Subject to and without waiving the general objections and any objections made pertaining to any corresponding Interrogatory response, Registrant shall produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 4:** 

All documents and things not identified in Registrant's responses to Petitioner's First Set of

Interrogatories served in connection with this Cancellation, which nonetheless were reviewed or relied upon in

preparing answers to said Interrogatories and/or which support Registrant's responses thereto.

Response:

Registrant objects to the extent this Request seeks information that is neither relevant to this matter,

nor reasonably calculated to lead to the discovery of admissible evidence. Registrant further objects to this

Request on the ground that complete compliance with "all documents and things" is overly broad and unduly

burdensome.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 5:** 

All documents Registrant intends to introduce into evidence in this proceeding.

Response:

Registrant objects to this Request under T.B.M.P. § 414(7) on the ground that a party is not obligated

to specify the evidence or documents it intends to present in advance of trial. Registrant further objects to this

Request on the ground that complete compliance with "all documents" is unduly burdensome.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

Request for Production No. 6:

All documents upon which Registrant intends to rely during the testimony period in support of

Registrant's case.

Response:

Registrant objects to this Request under T.B.M.P. § 414(7) on the ground that a party is not obligated

to specify the evidence or documents it intends to present in advance of trial. Registrant further objects to this

Request on the ground that complete compliance with "all documents" is unduly burdensome.

Subject to and without waiving the foregoing and the general objections, Registrant shall produce

appropriate documents as described in the Preliminary Statement.

**Request for Production No. 7:** 

All documents and things relating to each expert witness Registrant has engaged in connection with

this proceeding, including but not limited to, resumes, curricula vitae, references, and promotional matter, and

opinions, reports, exhibits, and communications concerning any issue presented or considered herein.

Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further

objects to this Request on the ground that complete compliance with "all documents and things" is overly

broad and unduly burdensome. Moreover, Registrant objects to the extent this Request seeks information that

is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing and the general objections, Registrant shall produce

appropriate documents as described in the Preliminary Statement.

**Request for Production No. 8:** 

Any written report, memorandum, opinion, or other written documents and things that were prepared

by any expert witness, regardless of whether Registrant presently intends to call such expert witness in this

proceeding.

Registrant objects to this Request under T.B.M.P. § 401.03 on the ground that a party is not obligated

to disclose information pertaining to non-testifying experts. Registrant further objects to the extent this

Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the

discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

provide an appropriate response as described in the Preliminary Statement

**Request for Production No. 9:** 

All documents and things relating to communications between Registrant and any third party,

including consumers, indicating or suggesting confusion between Registrant's Mark and the technology and

compositions that Petitioner terms RESTORADERM Technology or that the these third parties associate with

Petitioner.

Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further

objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 10:** 

All documents and things relating to communications between Registrant and any third party,

including consumers, inquiring as to whether items marketed under the mark "Restoraderm" or "Cetaphil

Restoraderm" are affiliated in any way with Petitioner.

Registrant objects to the extent this Request seeks information that is neither relevant to this matter,

nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 11:** 

All documents and things showing use of the term Restoraderm in commerce by Registrant in

connection with the sale, offer for sale, and/or distribution of any product or service prior to February 11, 2002,

and between then and February 28, 2002.

**Response:** 

Registrant objects to this Request on the ground that complete compliance with "all documents and

things" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 12:** 

All documents and things relating to the conception of the term "Restoraderm".

Response:

Subject to and without waiving the general objections, Registrant shall produce appropriate documents

as described in the Preliminary Statement.

**Request for Production No. 13:** 

All documents and things relating to the goods and services that are currently being marketed by

Registrant under or in connection with the term "Restoraderm".

Registrant objects to this Request on the ground that complete compliance with "all documents and things" is overly broad and unduly burdensome.

*y* .....

Subject to and without waiving the foregoing objection and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

Request for Production No. 14:

All documents and things relating to Registrant's first use of "Restoraderm" in commerce in

connection with a dermatology product.

Response:

Registrant objects to this Request on the ground that complete compliance with "all documents and

things" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

**Request for Production No. 15:** 

All drafts and execution copies of the 2002 Agreement and the 2004 Agreement, including exhibits

thereto.

Response:

Registrant objects to the extent this Request seeks information that is neither relevant to this matter,

nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objection and the general objections, Registrant shall

produce appropriate documents as described in the Preliminary Statement.

## **Request for Production No. 16:**

All documents and things relating to Registrant's return to Sköld of "Purchased Assets" as defined in §2.1 of the 2004 Agreement.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to this Request on the ground that complete compliance with "all documents and things" is overly broad and unduly burdensome. Moreover, Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Registrant further objects to the extent that the Request calls for a legal conclusion.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall produce appropriate documents as described in the Preliminary Statement.

# Request for Production No. 17:

Each United States patent and patent application assigned or licensed to Registrant that has claims, or if an application has or could have claims, covering a product that Registrant markets, had marketed or intends to market in the United States under the mark "Restoraderm" or "Cetaphil Restoraderm".

## Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent that the Request calls for a legal conclusion. Moreover, Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiving the foregoing objections and the general objections, Registrant shall produce appropriate documents as described in the Preliminary Statement.

Date: April 30, 2012

Respectfully submitted,

Lisa N. Congleton, Esq. Jeffrey M. Becker, Esq. Attorneys for Registrant HAYNES AND BOONE, LLP 2323 Victory Avenue, Suite 700

Dallas, Texas 75219 Telephone: 214-651-5262 Facsimile: 214-200-0765

 $lisa.congleton@haynesboone.com\\ D-2056709\_3.DOC$ 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld

Petitioner,

v.

Galderma Laboratories, Inc.
Registrant.

Cancellation No.: 92052897

Mark: RESTORADERM

Reg. Nos.: 2,985,751 and 3,394,514

# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 30th day of April, 2012, the foregoing *Registrant's Response* to Petitioner Sköld's First Set of Interrogatories and Request for Production of Documents and Things was served on Petitioner's counsel of record, via email to the following:

Arthur E. Jackson Moser IP Law Group artjcksn@gmail.com docketing@mtiplaw.com

Lisa N. Congleton

# Exhibit I – Jackson Declaration

(Registrant's Response to Petitioner Sköld's First Request for Admissions)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld

Petitioner,

Cancellation No.: 92052897

v.

Mark: RESTORADERM

Galderma Laboratories, Inc.

Registrant.

Reg. Nos.: 2,985,751 and 3,394,514

# REGISTRANT'S RESPONSE TO PETITIONER SKÖLD'S FIRST REQUEST FOR ADMISSIONS

Pursuant to 37 C.F.R. § 2.120, Rules 26 and 33 of the Federal Rules of Civil Procedure, and T.B.M.P. § 405.03(e), Galderma Laboratories, Inc. ("Registrant") herewith responds to Thomas Sköld's ("Petitioner") First Request for Admissions ("Request" or "Requests") as follows:

## **GENERAL OBJECTIONS**

- 1. Registrant objects to any specific Request to the extent that it seeks information subject to (i) the attorney-client privilege, (ii) the attorney work product doctrine, (iii) the protection afforded consulting experts pursuant to Federal Rule of Civil Procedure 26(b)(4)(B), (iv) the self-critical analysis privilege, (vi) the investigative privilege, (vi) the party communications privilege, (vii) the witness statement privilege, or (viii) any other privilege or protection afforded by state or federal law. To the extent that a Request can be construed as seeking information subject to such privileges, or any other privilege afforded by law, Registrant hereby claims such privilege and/or invokes the attorney work product doctrine.
- 2. Registrant expressly reserves the right to amend, supplement, or change its responses to Petitioner's First Requests for Admissions with information learned in the course of further investigation and discovery.

3. The objections listed above are not intended to be exhaustive. Registrant objects to each of the prefatory statements, definitions, and instructions, and Petitioner's Requests to the extent that they impose obligations upon Registrant that exceed those required by the Federal Rules of Civil Procedure, the Federal Rules of Evidence, Title 37 of the Code of Federal Regulations, any order of the Trademark Trial and Appeal Board, or any other applicable law.

Registrant incorporates by reference to each and every Response to Petitioner's Requests herein, the General Objections set forth above.

## RESPONSES TO REQUESTS FOR ADMISSIONS

# Request for Admission No. 1:

Registrant did not use the term Restoraderm in commerce in connection with any product prior to February 28, 2002.

#### **Response:**

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 2:

Registrant did not use the term Restoraderm in commerce in connection with any product prior to February 11, 2002.

## **Response:**

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 3:

Registrant did not use the term Restoraderm in commerce in connection with any product prior to September 11, 2001.

# Response:

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 4:

A U.S. Patent covering the Restoraderm Technology (here, the term used as defined in the 2004 Agreement) issued to Sköld on October 4, 2011, with Pat. No. 8,029,810.

## **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 5:

Any sale or assignment of the Restoraderm mark under either the 2002 or 2004 Agreement was contingent on the good faith development of at least some products contemplated under the agreements, and the consideration to Petitioner that would follow from such development.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent that the Request calls for a legal conclusion. Moreover, Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 6:

Registrant has never paid Petitioner contemplated in Section 2.3(c) of the 2004

Agreement for the s.

## Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

#### Request for Admission No. 7:

Registrant has never paid Petitioner even once contemplated in Section 4.1(b) of the 2004 Agreement for Product demonstrating clinical batch stability.

# **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

#### Request for Admission No. 8:

If the relationship contemplated by the 2004 Agreement had been fully consummated, Registrant would have paid Petitioner contemplated in Section 4.1(b) of the 2004 Agreement times, for a total

## Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion and a conclusion based on hypothetical facts. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 9:

Registrant has never paid Petitioner even once the \$134,000 dollars contemplated in Section 4.1(c) of the 2004 Agreement for

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 10:

If the relationship contemplated by the 2004 Agreement had been fully consummated, Registrant would have paid Petitioner contemplated in Section 4.1(c) of the 2004 Agreement times, for a total

# **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion and a conclusion based on hypothetical facts. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 11:

The monies contemplated to be paid to Petitioner by Registrant under Sections 2.3(c), 4.1(b) and 4.1(c) of the 2004 Agreement, but not paid, total

## **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 12:

There was no technical obstacle to developing at least five products to the point triggering all of the under Sections 4.1(b) and 4.1(c) of the 2004 Agreement[.]

#### Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 13:

Let us assume first a business plan based on licensing a medical technology and providing consulting services, and obtaining royalties and milestone payments of the relative scale reflected in the 2002 and 2004 Agreements. Let us further assume that the presentations to companies in 2010, 2011 and 2012 recited in the Recollections of Promotional Meetings provided with the First Updated Initial Disclosures represented bona fide efforts by those companies to explore licensing the medical technology. Then, given these assumptions, the use of a mark in connection with selling that technology and those consulting services, and in connection with such 2010, 2011 and 2012 meetings, would constitute a bona fide use of that mark in connection with that trade described herein.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion and a conclusion based on hypothetical facts. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 14:

Let us assume first a business plan based on licensing a medical technology and providing consulting services, and obtaining royalties and milestone payments of the relative scale reflected in the 2002 and 2004 Agreements. Let us further assume that the presentations to companies in 2010, 2011 and 2012 recited in the Recollections of Promotional Meetings provided with the First Updated Initial Disclosures represented bona fide efforts by those companies to explore licensing the medical technology. Then, given these assumptions, the use of a mark in connection with selling that technology and those consulting services, and in connection with such 2010, 2011 and 2012 meetings that were with U.S. headquartered companies, would constitute a bona fide use of that mark in connection with that trade described herein.

# **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 15:

On or before June 17, 2009, Registrant had decided to retain the Restoraderm mark, whether or not it continued developing the RESTORADERM Technology.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 16:

On or before August 17, 2009, Registrant had decided to retain the Restoraderm mark, whether or not it continued developing the RESTORADERM Technology.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 17:

Registrant terminated the 2004 Agreement pursuant to Section 8.5(b) thereof.

# Response:

Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 18:

Pursuant to Section 8.5(b) of the 2004 Agreement, Registrant was required to return to Sköld:



#### Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## **Request for Admission No. 19:**

Registrant never returned to Sköld "all goodwill" relating to the Restoraderm Intellectual Property, as required under Section 8.5(b) of the 2004 Agreement.

# **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

#### Request for Admission No. 20:

The Restoraderm mark was, as indicated by Registrants [sic] correspondence to Petitioner during many years (see, for Part A of the Petitioner's Initial Disclosure: items 1-3, 11, 14 and 15; for Part C of the First Updated Initial Disclosure: items 105, 108 and 110), related to the RESTORADERM Technology.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 21:

The RESTORADERM Technology was related to the Restoraderm Know How (as defined in the 2004 Agreement).

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 22:

The RESTORADERM Technology was related to the Restoraderm Intellectual Property (as defined in the 2004 Agreement), which Restoraderm Intellectual Property includes the Restoraderm Know How.

## Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

## Request for Admission No. 23:

The Restoraderm mark was related to the Restoraderm Intellectual Property.

# **Response:**

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 24:

The Restoraderm mark represents goodwill related to the Restoraderm Intellectual Property pursuant to Section 2.1 of the 2004 Agreement.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Registrant objects to the extent that the Request calls for a legal conclusion. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 25:

Registrant does not promote or sell any product marketed under the mark "Restoraderm" or "Cetaphil Restoraderm" as a treatment for any skin disorder.

# Response:

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 26:

Registrant does not promote or sell any product marketed under the mark "Restoraderm" or "Cetaphil Restoraderm" as a treatment for ezcema [sic].

# Response:

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 27:

No product being marketed by Registrant under the mark "Cetaphil Restoraderm" constitutes RESTORADERM Technology.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 28:

Registrant has never conducted a study of any product now being marketed under the mark "Restoraderm" or "Cetaphil Restoraderm" for use as a vehicle for delivering across the skin an active pharmaceutical substance.

# Response:

Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows:

# Request for Admission No. 29:

Registrant has never conducted a study of any product contemplated to be marketed under the mark "Restoraderm" or "Cetaphil Restoraderm" for use as a vehicle for delivering across the skin an active pharmaceutical substance.

Registrant objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objection and the general objections, Registrant responds as follows:

# Request for Admission No. 30:

Registrant has no Phase III or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including without limitation DESI pending, OTC Monograph, or GRASE), showing that product sold in the U.S. in 2011 under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment of Eczema.

#### Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows:

#### **Request for Admission No. 31:**

Registrant has no Phase III or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including without limitation DESI pending, OTC Monograph, or GRASE), showing that product sold in the U.S. in 2011 under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment of a skin disorder recognized as a treatment target by the U.S. Food and Drug Administration.

## Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows:

# Request for Admission No. 32:

Registrant has no Phase III or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including without limitation DESI pending, OTC Monograph, or GRASE), showing that a product intended to be, or later elected to be, sold under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment of Eczema.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows:

#### Request for Admission No. 33:

Registrant has no Phase III or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including without limitation DESI pending, OTC Monograph, or ORASE), showing that a product intended to be, or later elected to be, sold under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment of a skin disorder recognized as a treatment target by the U.S. Food and Drug Administration.

# Response:

Registrant objects to this Request on the grounds that it is vague and ambiguous. Registrant further objects to the extent this Request seeks information that is neither relevant to this matter, nor reasonably

calculated to lead to the discovery of admissible evidence. Subject to and without waiving the foregoing objections and the general objections, Registrant responds as follows:

# Request for Admission No. 34:

Registrant has elected to discontinue use of the mark "Restoraderm".

# Response:

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 35:

Registrant has elected to abandon the mark "Restoraderm".

# **Response:**

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

# Request for Admission No. 36:

Registrant has elected to replace the mark "Restoraderm" with "DERMACONTROL" or similar.

# **Response:**

Subject to and without waiving the general objections, Registrant responds as follows: Denied.

Date: April 30, 2012

Respectfully submitted,

Lisa N. Congleton, Esq. Jeffrey M. Becker, Esq.

Attorneys for Registrant

HAYNES AND BOONE, LLP 2323 Victory Avenue, Suite 700

Dallas, Texas 75219

Telephone: 214-651-5262 Facsimile: 214-200-0765

lisa.congleton@haynesboone.com D-2056649\_4.DOC

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld

Petitioner,

Cancellation No.: 92052897

v.

Mark: RESTORADERM

Galderma Laboratories, Inc.

Registrant.

Reg. Nos.: 2,985,751 and 3,394,514

# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 30th day of April, 2012, the foregoing *Registrant's Response* to Petitioner Sköld's First Request for Admissions was served on Petitioner's counsel of record, via email to the following:

Arthur E. Jackson Moser IP Law Group artjcksn@gmail.com docketing@mtiplaw.com

Lisa N. Congleton

# Exhibit J – Jackson Declaration

(Petitioner Sköld's Second Set of Interrogatories and Requests for Production of Documents and Things)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

# N THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Registration Nos. 2985751; and 3394514

Dated: August 16, 2005 & March 11, 2008, Respectively

Thomas Sköld,	)
Petitioner,	)
v.	) ) Cancellation No. 92052897
Galderma Laboratories, Inc., Registrant	)

BOX TTAB/FEE Commissioner for Trademarks 2900 Crystal Drive Arlington, VA 22202-3513

# PETITIONER SKÖLD'S SECOND SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

Pursuant to (a) 37 C.F.R. §§ 2.116(a) and 2.120, Fed. R. Civ. P. 33, and TBMP §§ 403.02 and 408.01, and (b) 37 C.F.R. § 2.120, Fed. R. Civ. P. 34, and TBMP §§ 403.03 and 408.01, Petitioner Thomas Sköld herewith serves the following interrogatories and requests for production to Registrant Galderma Laboratories, Inc. ("Galderma") and requests that Registrant respond fully and separately in writing under oath by a duly authorized officer or agent within thirty (30) days after service. Each interrogatory and request for production shall be deemed continuing in nature, and Registrant shall update, revise, and otherwise keep current, any information provided in response to each interrogatory as facts or circumstances become known or change, in accordance with Fed. R. Civ. P. 26(e). Registrant shall send the requested responses to Arthur E. Jackson, Moser Taboada, 1030 Broad Street, Shrewsbury, NJ 07702.

# **INSTRUCTIONS**

1. Unless otherwise indicated, these interrogatories and requests for documents apply to the period January 1, 2001 to the date of the trial of this proceeding.

- 2. These interrogatories are directed to Registrant (as defined below) and cover all information and documents within the possession, custody or control of Registrant, its employees, agents, attorneys, representatives, or anyone acting on her behalf.
- 3. Each interrogatory and request for production is expressly made continuing pursuant to Rule 4:17-7 and 4:17-8. If information or documents responsive to any part of an interrogatory or request for documents are not presently known or available or if additional responsive information or documents become known or available, then furnish all information and documents currently known and available, specify each portion of the interrogatory or request for documents cannot be completely answered, and thereafter promptly respond to the entire interrogatory or request for documents by supplementing your answer within a reasonable time from the moment at which any additional responsive information or documents become known or available.
- 4. To the extent any objection is made to any of these interrogatories or requests for documents, you must respond to so much of each such interrogatory or request for production to which no objection is made. If any objection on the grounds of vagueness, overbreadth, or any similar ground is made, you must respond to the Request for Production as narrowed to conform to your objection. If any response to an interrogatory or production requested is withheld on the basis of any claim of privilege or work product, Registrant is requested to submit in lieu of any such production a written statement no later than the date of production: (1) identifying the person who prepared or authorized the document, and if applicable, the date on which the document was prepared or transmitted; (2) identifying the subject matter of the document; (3) describing the document in nature (e.g., letter, email, etc.); (4) stating why the document is claimed to be privileged or to constitute work product; and (5) identifying the paragraph of this request to which the document relates. If any document relates in any way to a meeting or to any conversation, all participants in the meeting or conversation are to be identified.
- 5. If any document responsive to a request was formerly in the possession, custody, or control of Plaintiffs but has been lost or destroyed, Plaintiffs are to submit in lieu of each item a written statement which (a) describes in detail the nature of the item and its contents; (b) identifies the person who prepared or authored the item, and if applicable, the person to whom the item was sent; (c) specifies the date on which the item was prepared or transmitted or both; and (d) specifies the date on which the item was lost or destroyed, and, if destroyed, the

conditions of or reasons for such destruction and the persons requesting and performing the destruction.

### **DEFINITIONS**

The following definitions apply to, and are deemed to be incorporated into, each of the requests herein.

- 1. "2002 Agreement" means the agreement entitled "Co-Operation, Development and Licensing Agreement" executed by and between CollaGenex Pharmaceuticals Inc. and Petitioner and made effective as of February 11, 2002.
- 2. "2004 Agreement" means the agreement entitled "Asset Purchase and Product Development Agreement" executed by and between CollaGenex Pharmaceuticals Inc. and Petitioner and made effective as of August 19,2004.
- 3. "Registrant", or "you" or "your" or "yours" shall refer to and include Registrant, as well as agents, servants, employees, associates, investigators, attorneys, representatives, shareholders, directors, officers and all others who may have obtained information for or on behalf of those named above. "Registrant" includes Galderma or its predecessor in interest, Collagenex Pharmaceuticals, Inc. ("Collagenex").

### 4. "Identify":

- 4.1. When used in reference to a natural person means: that person's full name, present or last known business and residence address, present or last known business and residence telephone number, present or last known occupation, employer, and position and that person's occupation or position during the time relevant to the particular interrogatory.
- 4.2. When used in reference to an entity means: its full and complete name, its type of entity (i.e., corporation, partnership, unincorporated association, trade name, etc.), the location of its principal place of business, its mailing address, and its telephone number.
- 4.3. When used in reference to a document means: a description of the type of document, the identity of the person or persons who authored, prepared, signed, and received the document, the date, title, and general description of the subject matter of the document, present location or custodian of the original and each copy of the document,

the identity of any persons who can identify the document, and if a privilege is claimed, the specific basis for such claim, in addition to the information set forth above.

- "Document" or "documents" means any written, typed, printed, recorded or graphic matter (including e-mails, instant messages, and other forms of electronic communications or recordings), however produced or reproduced, of any type or description, regardless of origin or location, including without limitation all correspondence, records, diagnostic examination and related reports, tables, charts, analyses, graphs, schedules, reports, memoranda, notes, lists, calendar and diary entries, letters (sent or received), telegrams, telexes, messages (including, but not limited to, reports of telephone conversations and conferences), voicemail messages, e-mail messages, instant messages, studies, books, periodicals, magazines, booklets, circulars, bulletins, instructions, papers, files, minutes other communications (including, but not limited to, inter- and intra-office communications), questionnaires, contracts, memoranda or agreements, assignments, licenses, ledgers, books of account, orders, invoices, statements, bills, checks, vouchers, notebooks, receipts, acknowledgements, data processing cards, computer-generated matter, photographs, photographic negatives, phonograph records, tape recordings, wire recordings, audio recordings, magnetic or mechanical recordings, transcripts or logs of any such recordings, all other data compilation from which information can be obtained or translated if necessary, and any other tangible thing of a similar nature...
- 6. The word "describe", used in connection with any act, occurrence, or physical facts, shall include but not be limited to the following: the identity of every person known to have been involved in or to have witnessed the act or occurrence, the date or dates of any such act or occurrence, and a description of any documents, records, or things documenting or involved in such act, occurrence, or fact.
- 7. Petitioner's RESTORADERM Technology is based on (a) compositions of stratum corneum lipids (phospholipids/ceramide/ cholesterol/fatty acid), and (b) the presence of different macromolecular aggregates formed of the lipids. References herein to the "RESTORADERM Technology" are references to technology encompassing (a) and (b), unless a different meaning is specified.

### **INTERROGATORIES**

### **Interrogatory No. 36:**

Describe in detail all facts and identify all documents and things showing that Registrant used the term Restoraderm in commerce in connection with any product prior to February 28, 2002.

### **Interrogatory No. 37:**

Describe in detail all facts and identify all documents and things showing that Registrant used the term Restoraderm in commerce in connection with any product prior to February 11, 2002.

### **Interrogatory No. 38:**

Describe in detail all facts and identify all documents and things showing that Registrant used the term Restoraderm in commerce in connection with any product prior to September 11, 2001.

### Interrogatory No. 39:

Interrogatory No. 40:	
the 2004 Agreement for	·.
has paid Petitioner any or all of	payments contemplated in Section 4.1(b) of
Describe in detail all facts and ide	entify all documents and things showing that Registrant

Describe in detail all facts and identify all documents and things showing that Registrant has paid Petitioner any or all of payments contemplated in Section 4.1(c) of the 2004 Agreement for .

Interrogatory No. 41:

Describe in detail all facts and identify all documents and things showing that Registrant terminated the 2004 Agreement other than pursuant to Section 8.5(b) thereof, with such description explaining any apparent or clear inconsistency with Exhibit 5 to Petitioner's Amended Complaint.

### **Interrogatory No. 42:**

Describe in detail all facts and identify all documents and things showing that Registrant has, on or after January 1, 2009, conducted a study of any product contemplated to be marketed under the mark "Restoraderm" or "Cetaphil Restoraderm" for use as a vehicle for delivering across the skin an active pharmaceutical substance.

### **Interrogatory No. 43:**

Describe in detail all facts and identify all documents and things showing that Registrant has conducted a Phase II and/or Phase III study or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including if relevant and without limitation DESI pending, OTC Monograph, or GRASE), showing that any product sold or intended to be sold in the U.S. in 2009 or later under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment for Eczema.

### **Interrogatory No. 44:**

Describe in detail all facts and identify all documents and things showing that Registrant has conducted a Phase II and/or Phase III study or comparably rigorous studies in support a New Drug Application under the U.S. Food and Drug Act, or in support a comparable regulatory approval (including if relevant and without limitation DESI pending, OTC Monograph, or GRASE), showing that any product sold or intended to be sold in the U.S. in 2009 or later under the mark "Restoraderm" or "Cetaphil Restoraderm" provides a treatment of a skin disorder recognized as a treatment target by the U.S. Food and Drug Administration.

### **Interrogatory No. 45:**

Describe in detail all facts and identify all documents and things showing that the FDA Compliance Officer (as defined in the Petitioner's First Set of Interrogatories), or his predecessor in that position, has represented to the U.S. Food and Drug Administration that a product sold under the mark "Cetaphil Restoraderm" in the United States during 2012 or earlier is a "therapeutic skin care preparation" and/or provides a "treatment of skin disorders."

### **Interrogatory No. 46:**

Describe in detail all facts and identify all documents and things showing that the FDA Compliance Officer (as defined in the Petitioner's First Set of Interrogatories), or his predecessor in that position, intends to represent to the U.S. Food and Drug Administration that a product sold under the mark "Cetaphil Restoraderm" in the United States during 2012 or earlier is a "therapeutic skin care preparation" and/or provides a "treatment of skin disorders."

### **Interrogatory No. 47:**

Describe in detail all facts and identify all documents and things showing that any document represented as originating from Registrant (including the Press Release that is Exhibit 1 to the Amended Petition for Cancellation), or as sent to Registrant, and provided to Registrant

with the Petition for Cancellation, the Amended Petition for Cancellation, the Petitioner's Initial Disclosure, or the Petitioner's First Updated Initial Disclosure, is other than a true and correct copy.

### **Interrogatory No. 48:**

Please identify each document represented as originating from Registrant (including the Press Release that is Exhibit 1 to the Amended Petition for Cancellation), or as sent to Registrant, and provided to Registrant with the Petition for Cancellation, the Amended Petition for Cancellation, the Petitioner's Initial Disclosure, or the Petitioner's First Updated Initial Disclosure, that is a true and correct copy.

### **REQUESTS FOR PRODUCTION**

### Request for production No. 18:

All documents and things identified in Registrant's responses to Petitioner's Second Set of Interrogatories set forth above.

### Request for production No. 19:

All documents and things not identified in Registrant's responses to Petitioner's Second Set of Interrogatories served in connection with this Cancellation, which nonetheless were reviewed or relied upon in preparing answers to said Interrogatories and/or which support Registrant's responses thereto.

Respectfully submitted,

Date: May 11, 2012

Arthur E. Jackson, Ph.D., Esq. New Jersey Bar No. 00288-1995 ajackson@moseriplaw.com MOSER IP LAW GROUP 1030 Broad Street, Suite 203 Shrewsbury, NJ 07702 (732) 935-7100 (732) 935-7122 Attorney for Petitioner

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld,	)
Petitioner,	)
	)
v.	)
	) Cancellation No. 92052897
Galderma Laboratories, Inc.,	)
Registrant	)
	)

### **CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing Petitioner Sköld's Second Set of Interrogatories, was sent by email on this 11<sup>th</sup> of May, 2012 to:

Jeff.Becker@haynesboone.com

# Exhibit K – Jackson Declaration

(Abstracts of Diamond et al. and Grunkemeier et al.)

Sköld v. Galderma Cancellation No. 92052897 Re Registration Nos. 2985751 and 3394514

#### Annals of Internal Medicine

www.annals.org

Ann Intern Med March 1, 1983 vol. 98 no. 3 385-394

#### **Academia and Clinic**

### Clinical Trials and Statistical Verdicts: **Probable Grounds for Appeal**

GEORGE A. DIAMOND, M.D.; and JAMES S. FORRESTER, M.D.

+ Author Affiliations

#### Abstract

Conventional interpretation of clinical trials relies heavily on the classic p value. The p value, however, represents only a false-positive rate, and does not tell the probability that the investigator's hypothesis is correct, given his observations. This more relevant posterior probability can be quantified by an extension of Bayes' theorem to the analysis of statistical tests, in a manner similar to that already widely used for diagnostic tests. Reanalysis of several published clinical trials according to Bayes' theorem shows several important limitations of classic statistical analysis. Classic analysis is most misleading when the hypothesis in question is already unlikely to be true, when the baseline event rate is low, or when the observed differences are small. In such cases, false-positive and falsenegative conclusions occur frequently, even when the study is large, when interpretation is based solely on the p value. These errors can be minimized if revised policies for analysis and reporting of clinical trials are adopted that overcome the known limitations of classic statistical theory with applicable bayesian conventions.

#### Article and Author Information

From the Division of Cardiology, Department of Medicine, Cedars-Sinai Medical Center, UCLA School of Medicine; Los Angeles, California.

© 1983 American College of Physicians

#### Articles citing this article

Multiplicity-calibrated Bayesian hypothesis tests

Biostatistics July 1, 2010 11:473-483

Abstract Full Text Full Text (PDF)

What is the Value of a p Value?

Ann. Thorac. Surg. May 1, 2009 87:1337-1343

Abstract Full Text Full Text (PDF)

{beta}-Blockers in Congestive Heart Failure: A Bayesian Meta-Analysis

ANN INTERN MED April 3, 2001 134:550-560

Abstract Full Text Full Text (PDF)

Toward Evidence-Based Medical Statistics. 1: The P Value Fallacy ANN INTERN MED June 15, 1999 130:995-1004

Abstract Full Text Full Text (PDF)

5/17/2012 10:37 AM 1 of 2

### Toward Evidence-Based Medical Statistics. 2: The Bayes Factor

ANN INTERN MED June 15, 1999 130:1005-1013

Abstract Full Text Full Text (PDF)

#### Central Venous Catheter Care in Parenteral Nutrition: A Review

JPEN J Parenter Enteral Nutr March 1, 1987 11:190-201

Abstract Full Text (PDF)

#### Posterior Probability in Clinical Trials

ANN INTERN MED March 1, 1984 100:457

Abstract Full Text (PDF)

#### Analysis of Data from Clinical Trials

ANN INTERN MED December 1, 1983 99 874-875

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Ann Thorac Surg 2009;87:1337-1343. doi:10.1016/j.athoracsur.2009.03.027 © 2009 The Society of Thoracic Surgeons

### The Statistician's Page

## What is the Value of a *p* Value?

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Successful publication of a research study usually requires a small p value, typically p < 0.05. Many clinicians believe that a p value represents the probability that the null hypothesis is true, so that a small p value means the null hypothesis must be false. In fact, the p value provides very weak evidence against the null hypothesis, and the probability that the null hypothesis is true is usually much greater than the p value would suggest. Moreover, even considering "the probability that the null hypothesis is true" is not possible with the usual statistical setup and requires a different (Bayesian) statistical approach. We describe the Bayesian approach using a well-established diagnostic testing analogy. Then, as a practical example, we compare the p-value result of a study of aprotinin-associated operative mortality with the more illuminative interpretation of the same study data using a Bayesian approach.

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Eur J Cardiothorac Surg, November 1, 2009; 36(5): 875 - 876.

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G. Lindvall, U. Sartipy, S. Bjessmo, P. Svenarud, B. Lindvall, and J. van der Linden

Aprotinin reduces the antiplatelet effect of clopidogrel Interact CardioVasc Thorac Surg, August 1, 2009; 9(2): 178 - 181. [Abstract] [Full Text] [PDF]

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